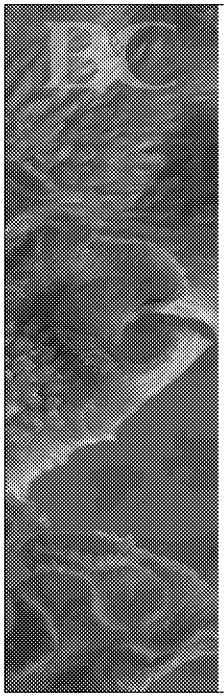

Living with SNURs

- Submitters
  - Work with EPA on conditions
  - Communicate with supply chain
- Develop/upgrade systems for recordkeeping
  - Possible that minimal upgrade is necessary
- Develop/upgrade processes/systems for Section 12(b) reporting

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Thank You

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Part 4: TSCA Risk Evaluations
Wednesday, May 20, 2020 from 12:00 – 1:30 PM ET
Moderator: Suzanne Hartigan, ACC
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Mike Walls

VP, Regulatory & Technical Affairs

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Lynn Dekleva

Associate Deputy Assistant Administrator for New Chemicals

U.S. EPA, OCSPP

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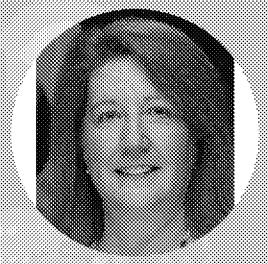

Tala Henry

Deputy Director

U.S. EPA, OPPT

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Ritesh Tiwari
Chemical Engineer, RAD
U.S. EPA, OPPT

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Rich Engler

Director of Chemistry

Bergeson & Campbell, P.C.

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Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 5/13/2020 2:47:02 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Tiwari, Ritesh [tiwari.ritesh@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Slides for today's webinar
Attachments: Part 3_TSCA New Chemicals_No Ritesh.pptx

If you'd like to familiarize yourself with the slide deck, the combined presentation deck is attached. There is a placeholder for Ritesh's slides, FYI.

In the meantime, please let me know if you have any questions or if we can be of assistance. Mike
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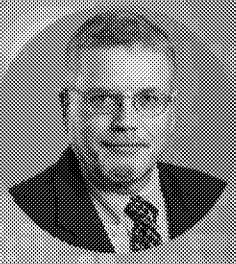

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VP, Regulatory & Technical Affairs
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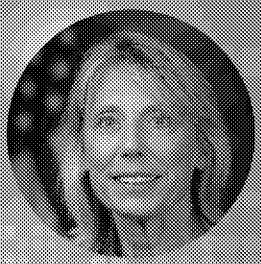

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2016 TSCA section 5 Amendments

- Recognized critical role of section 5 in innovation and competitiveness
- Significant changes:
  - EPA must have sufficient information to make a decision
  - Requires attention to sensitive subpopulations
  - Reinforces transparency objective

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Implementation Considerations

- Number of submissions
- Pace of reviews
- Scientific basis for decisions
  - Statutory requirements to apply best available science, using weight of the scientific evidence
- Process improvements

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New Chemicals

Lynn Ann Dekleva
Associate Deputy Assistant Administrator
for New Chemicals

New Chemical Process Improvements

- Lean Activities
- Automation of Manual Processes
- Upgraded Case Tracking
- Deployment of Dedicated Resources
- Enhanced Submitter Engagement
- Utilization of Unilateral Orders
- Greater Transparency

Shared Commitment
"Drive to 90"


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GlobalChem
May 13, 2020

TSCA New Chemical Review Science Approaches

Tala R. Henry, Ph.D.
Deputy Director
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency

New Chemical Hazard Assessment: Approach

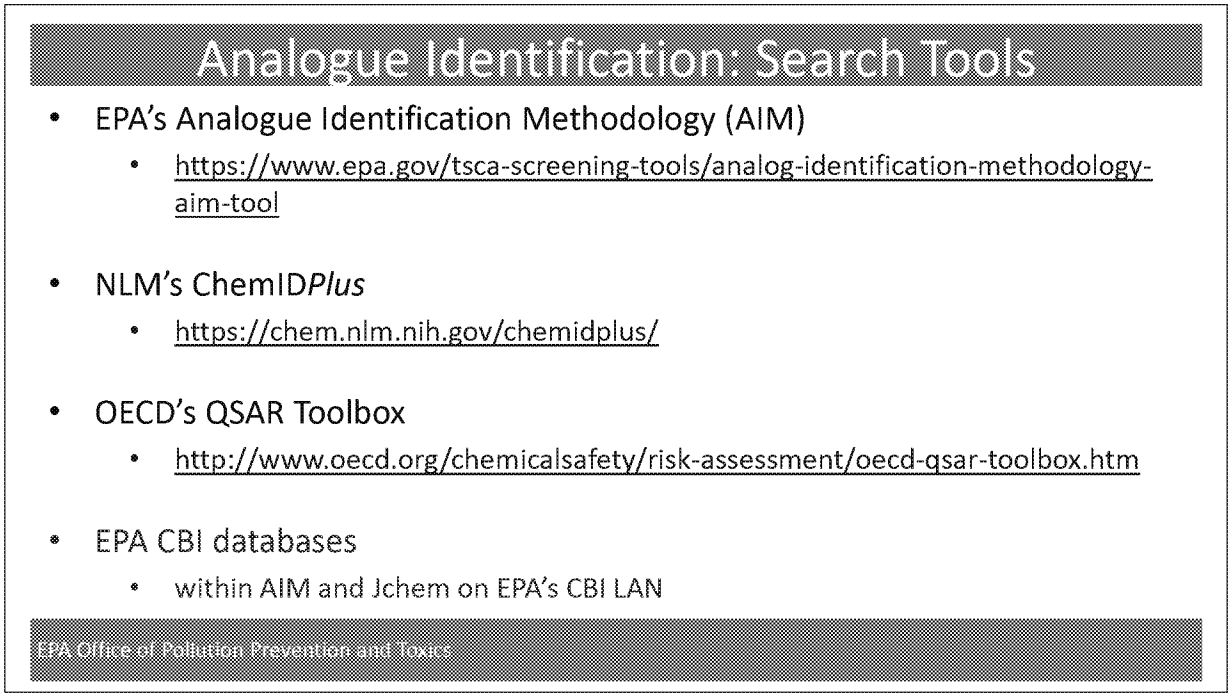
- Data Preference: Chemical-specific test data > Analogue data > Modeled data
- Submitted data/studies: "Submitted health and environmental effects data/studies: Only requirement is for existing data in the possession or control of the submitter" per 40 CFR § 720.45
- EPA receives little data; in vitro, short-term >>> in vivo, subchronic/chronic

Analogue Identification

- Analogue Data: EPA Considers:
  - Physical-chemical properties (*e.g.*, log K_{ow}, water solubility, and melting point), presence and position of reactive functional groups, *etc.*
  - Potential metabolites or degradates (*e.g.*, hydrolysis products)
  - TSCA New Chemicals Program (NCP) Categories
  - Structural alerts for toxicity
  - Identify hazards associated with the category and/or structural alerts

Analogue Identification

- Analogues Identified:
  - To characterize hazards
  - To identify Points of Departure for quantifying risks
  - Even when data are submitted on the new chemical (rare to get robust set of hazard endpoints)
  - By SUBMITTER, EPA chemists, or EPA toxicologists



The Analog Identification Methodology (AIM) is a software program that facilitates analog analysis and data identification in support of chemical assessment or read-across approaches

Key characteristics of the program include:
Ability to conduct comprehensive structural analysis of chemicals using over 700 individual atoms, groups and super fragments indexed in a predefined database
Uses structural analysis to match potential analogs from an inventory of over 86,000 chemicals with publicly available measured data and links to the data sources
Ability to recode defined substitutions or exclusion rules for the refinement of analog search strategies

ChemIDplus is a free, web search system that provides access to the structure and nomenclature authority files used for the identification of chemical substances cited in National Library of Medicine (NLM) databases. ChemIDplus also has structure searching and direct links to resources at NLM, federal agencies, U.S states, and scientific sites. The database contains more than 400,000 chemical records, of which over 300,000 include chemical structures.

Analogue Data Sources

- EPA IRIS: Integrated Risk Information System
- EPA PPRTVs: Provisional Peer-Reviewed Toxicity Values
- EPA ChemView – for HPVIS and full 8e studies
- EPA Comptox – for ACToR and Comptox in vitro bioassay data; can also be used for analogues/read-across
- EPA NCELS: New Chemical Exposure Limits
- EPA CBI databases: AIM and JChem
- ATSDR Toxicological Profiles:
- CalEPA Chemicals Database
- ECHA Registered Substances Database
- HERA Project: Human and Environmental Risk Assessment
- INCHEM: Internationally Peer reviewed Chemical Safety Information
- OECD Existing Chemicals Database: HPV SIDS Assessments
- HSDB (tox summary data) and ChemID*Plus*

Information Submitters Should Consider / Provide

- Justification for use of the analogue for the endpoint(s) identified, *e.g.*, structural and biological.
- Full chemical name and CAS numbers of all analogues.
- Clear structural representation of all analogue(s).
- Full studies for any analogues, if available, to better ensure efficient consideration by EPA.

Information Submitters Should Consider/Provide

- Whether the structure of the new chemical substance has any structural alerts.
- Whether the new chemical substance has been submitted to/reviewed by another international agency.
- Explanation or rationale for why any toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation.
- Particle size/droplet size information for the new chemical substance would aid the assessment of respirability.
- Statement about the applicability of *in silico*, *in vitro*, or other non-vertebrate test data for use with evaluating the new chemical substance.

EPA Office of Pollution Prevention and Toxics

Whether the structure of the new chemical substance has any structural alerts EPA's initial hazard flag.

Whether the new chemical substance has been submitted to/reviewed by another international agency If data in ECHA Database, EPA will look there.

Explanation or rationale for why any toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation refine exposure pathways/routes

Particle size/droplet size information for the new chemical substance would aid the assessment of respirability.

in silico, in vitro, or other non-vertebrate test can inform evaluation their chemical substance.

Innovative Assessment Approaches

- Draft interim science policy for skin sensitization, replaces animal testing with new approach methodologies (NAMs)
- Lung Effect Categories with industry participation and engagement
  - **Short-term reactive process:** Polycationic Substances (Cationic Binding) & General Surfactants
  - **Longer-term physical process:** Insoluble Polymer Lung Overload
- Working with ACC panel members to develop a proposed respiratory sensitization framework for newer isocyanate chemistries

Innovative Assessment Approaches: Use of NAMs

- OPPT has utilized various NAMs to exclude chemical substances from specific chemical categories (*e.g.*, polymer lung overload)
  - On April 1, 2020, EPA issued a proposed rule to revoke a significant new use rule (SNUR) for a new chemical substance, based on the results of a biosolubility study. See: https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06442.pdf
  - The original SNUR would have required a subchronic inhalation toxicity study in order to use the chemical substance in a manner inconsistent with the original new chemical substance submission
  - Measured Biosolubility Data and refined manufacturing process information demonstrated the chemical would not present a hazard concern for lung overload

Thank You

QUESTIONS?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Ritesh Slides


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GlobalChem Webinar Series Part 3: TSCA New Chemicals

May 13, 2020

Richard E. Engler, Ph.D.
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Significant New Use Rules (SNUR)

- SNURs are up since the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg)
- Prior to 2016, 10-20% of premanufacture notices (PMN) were regulated (Section 5e or non-5e SNURs)
- Immediately after enactment
  - >90% valid PMNs were receiving "may present" determinations with Section 5e orders

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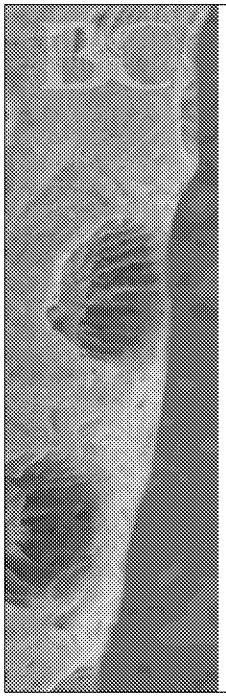

Solutions

- Polymer exemption flag
- Non-order SNURs
  - Reduces the need for orders, but still represent regulations and a burden on the supply chain (recordkeeping, Section 12(b), Chemical Data Reporting (CDR) threshold)
- Changes in what is “reasonably foreseeable”
  - Routine use of gloves, goggles, and general dermal protection in industrial settings
  - Requirement to specify “impervious” gloves
- Currently, about half of the PMNs are receiving orders/SNURs

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Suggestions for the U.S. Environmental Protection Agency (EPA)

- Explain better its reasoning on what is reasonably foreseeable
- Give better guidance on how a submitter can limit what EPA foresees
  - Level of supporting evidence

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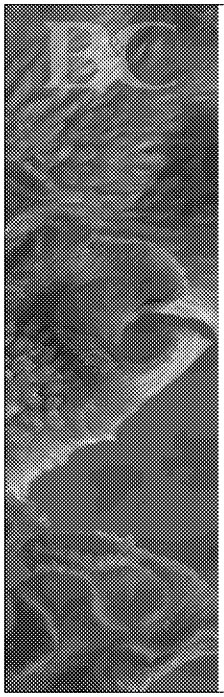

Living with SNURs

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- Develop/upgrade processes/systems for Section 12(b) reporting

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Thank You

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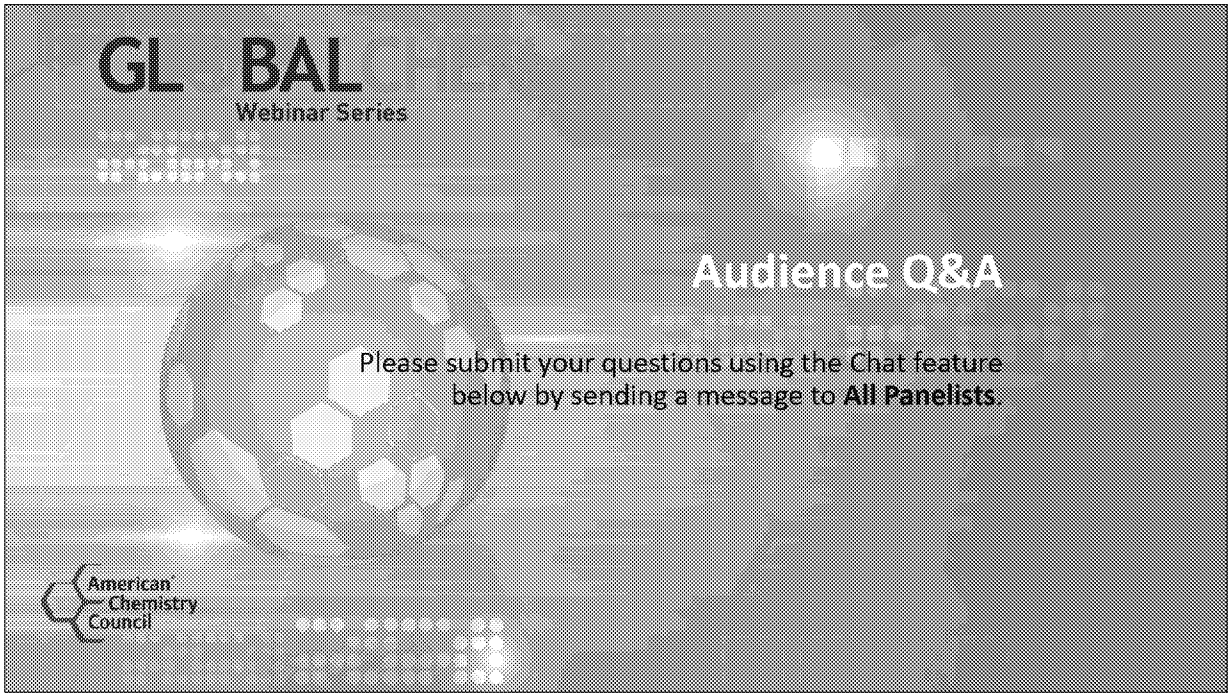
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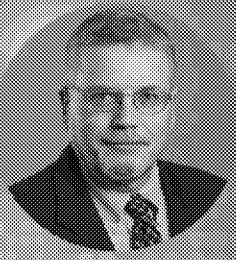

Mike Walls
VP, Regulatory & Technical Affairs
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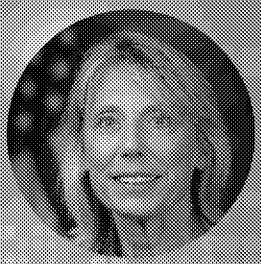

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Rich Engler
Director of Chemistry
Bergeson & Campbell, P.C.

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Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 5/5/2020 6:26:21 PM
To: Henry, Tala [Henry.Tala@epa.gov]; Tiwari, Ritesh [tiwari.ritesh@epa.gov]
CC: Dekleva, Lynn [dekleva.lynn@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]; Gale, Kat [Kat_Gale@americanchemistry.com]
Subject: GlobalChem Webinar on New Chemicals, Wednesday, May 13, 12 to 1:30 p.m.
Attachments: GlobalChem Webinar Series Speaker Guide_0513-New Chemicals_DRAFT 20200504.DOCX

Tala and Ritesh: Lynn just shared the great news that you will be able to join us for our GlobalChem webinar on the new chemicals program on Wednesday, May 13 at 12 noon. On behalf of ACC, I want to thank you for your time and willingness to share your experience and expertise.

I have attached for your information our speaker guidance material that I have already shared with Lynn and Rich Engler. On page 3, you'll see information on a pre-webinar call tentatively scheduled for Monday, May 11, from 12-12:30 p.m. I hope you will be able to join us for that call, to give us an opportunity to talk through the session as a group. If you would like to use powerpoint slides, we'd appreciate getting them by May 11 so that we can upload them to our system. I also included on page 3 a rough outline of how the session might flow, and we can discuss that on Monday.

If I can provide any additional information, or be of any assistance, please let me know. If you need to reach me by phone, my number is Ex. 6 Personal Privacy (PP) - personal phone

Thanks again! Regards, Mike

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To that end, ACC is hosting a weekly, 90-minute webinar on topics drawn from the GlobalChem 2020 agenda each Wednesday at 12:00 pm ET. These webinars are designed to address major developments in chemicals management, and provide participants a chance to engage with policymakers and other key experts throughout the chemical industry value chain.

Attendee Profile

GlobalChem attracts industry professionals that specialize in government affairs, international affairs, regulatory matters, trade, product stewardship, toxicology and EH&S, among others.

Registration

As a speaker, your registration for the webinar series is free. ACC Meeting Services will manage your registration on your behalf and you are welcome to participate in any other session offered during the series at no cost.

Bios & Headshot

Speakers are asked to submit a brief bio and a headshot that will be used to promote the webinar on [HYPERLINK "http://www.globalchem.org"]. Professional/social networking info may also be submitted (e.g., LinkedIn, Twitter).

Webinar Presentation Tips

- Virtual events rely heavily on keeping the audience's attention. If possible, powerpoint slides should be kept to a minimum. **The focus of any presentation should be the speaker and the content given, not the slides.** Be mindful of your presentation length and slide legibility. Avoid text-heavy slides and use large font sizes. Due to the nature of the virtual event, screen space is limited, and any graphics should be easily visible and compelling for attendees.

- Build in **5** minutes at the end of your presentation session for a question and answer period. If part of a panel discussion, your facilitator will assist you in opening this dialogue after all presenters have spoken.

- ACC reserves the right to contact speakers if we determine that any edits to presentation materials are necessary. While speakers are free to use their own PPT templates, it is recommended that you have a legal review performed with your internal attorney(s) prior to submitting it for the webinar.

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Intent to Record Webinar:

ACC intends to record each session of the 2020 GlobalChem Webinar Series for later viewing. The recorded sessions may capture PowerPoint presentation slides and audio of moderators and presenters, and/or still photographs of moderators and presenters.

ACC requests that moderators and presenters agree to be identified by name and that their materials may be included in the recording. Presenters may request that specific material be withheld, or that their material or audio not be included in the final recording.

The recordings in no way restrict the publication or dissemination of any material in any form by moderators or presenters, or others authorized by moderators or presenters.

General Technology Tips

ACC recognizes the challenges we are all facing as we weather the COVID-19 storm. Here are a few tips on technology that will facilitate a successful webinar:

- Optimize Your Home Network
  - When possible, plug directly into your router for a hardwired connection.
  - If on W-Fi, access your network's 5G band vs. the standard 2.4G.
  - The ideal distance from your router is 5-8 feet to achieve the strongest wireless signal.
  - Minimize network traffic by limiting family members' usage of streaming services or other video conferencing tools during your session.

- Camera & Background
  - Maintain a neutral background with minimal distractions.
  - Avoid any light source BEHIND you such as a lamp or window with the sun shining through. This causes some cameras to adjust its exposure settings and could lead to a dark picture.
  - Maintain a good ratio of headspace vs. background space.

- Microphone
  - When possible, use a dedicated, hardwired headset for the best audio results.

- Connectivity Issues
  - If you experience a temporary lack of connectivity, simply try to reconnect while your moderator fills in for you.
  - If your connectivity issue is more severe, dial into the audio only portion of the webinar to continue participating without video. Having a printed out version of your talk and slides in advance is helpful.

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Your Participation

- **Session: TSCA New Chemicals**
  This webinar will address key changes in the section 5 program, and challenges faced by EPA and submitters, including information requirements, assessment of risks, and practical tips.

- **Date & Time: Wednesday, May 13, 2020, 12:00-1:30 PM**
  Please log into the webinar no later than 11:30 am

  - **WEBEX URL:** [HYPERLINK
    Ex. 6 Personal Privacy (PP) - conference code/call in number
    EVENT PASSWORD: Ex. 6 Personal Privacy (PP) - conference code/call in number
  - **Audio Only Dial In:** Ex. 6 Personal Privacy (PP) - conference code/call in number
    Access Code: Ex. 6 Personal Privacy (PP) - conference code/call in number

- **Pre-Webinar Group Dry Run: Monday, May 11, 12:00-12:30 PM**
  - Please use the same login link above to join this practice session. During this time, we will go over the flow of the webinar, confirm video and audio capabilities and answer any question you may have.

- **Session Organizer: Mike Walls, ACC**

- **Moderator: Mike Walls, ACC**

- **Speakers:**
  - **Lynn Dekleva, U.S. EPA**
  - **Rich Engler, Bergeson & Campbell**
  - **EPA?**
  - **EPA?**

- **Webinar Format:**
  (Adjust as necessary by Organizer or Moderator)

  - **12:00 – Welcome & Housekeeping Items by Schubert Fabros**
  - **12:05 – Housekeeping & Opening Remarks from Mike Walls & Introduction of Panel**
  - **12:10 – Lynn Dekelva Remarks with PPT**
  - **12:25 – Other EPA speakers**
  - **12:50 – Rich Engler Remarks with PPT**
  - **1:05 – Short Roundtable Discussion from Panel [?], Moderated by Mike Walls**
  - **1:10 – Q&A Session from Audience (curated by Kat Gale)**
  - **1:30 – Closing & Thank You**

Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 5/4/2020 7:58:42 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]
CC: Gale, Kat [Kat_Gale@americanchemistry.com]
Subject: GlobalChem Webinar on New Chemicals, Wednesday, May 13, 12 to 1:30 p.m.
Attachments: GlobalChem Webinar Series Speaker Guide_0513-New Chemicals_DRAFT 20200504.DOCX

Lynn and Rich: Thank you for your willingness to participate in our upcoming GlobalChem webinar on the new chemicals program. I have attached for your information some speaker guidance; page 3 contains information on a pre-webinar call tentatively scheduled for Monday, May 11, from 12-12:30 p.m. That will give us an opportunity to talk through the session. If you would like to use powerpoint slides, we'd appreciate getting them by May 11 so that we can upload them to our system. I also included on that page a rough outline of how the session might flow, and we can discuss that on Monday.

Lynn, in my discussion with Rich, he noted an interest in addressing the following issues: how much information/evidence does RAD need to overcome the assumptions in the generic scenarios; confidential business information, and SNURs. Added to the case studies that we talked about, we'll have a pretty comprehensive session!

I look forward to a great webinar with you, and I very much appreciate your willingness to participate. If I can provide any additional information, or be of any assistance, please let me know. If you need to reach me by phone, my number is Ex. 6 Personal Privacy (PP) - personal phone

Thanks again! Regards, Mike

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Webinar Series

Although the 2020 GlobalChem Conference & Exhibition was cancelled as a result of the COVID-19 pandemic, the American Chemistry Council (ACC) is committed to engaging its GlobalChem audience in a meaningful and impactful way during these difficult times. ACC holds GlobalChem to a high standard as the premier forum for information sharing in the chemicals management arena and the efforts made in shaping the 2020 conference has reinforced ACC's vision of providing a program with a high level of value for the industry.

To that end, ACC is hosting a weekly, 90-minute webinar on topics drawn from the GlobalChem 2020 agenda each Wednesday at 12:00 pm ET. These webinars are designed to address major developments in chemicals management, and provide participants a chance to engage with policymakers and other key experts throughout the chemical industry value chain.

Attendee Profile

GlobalChem attracts industry professionals that specialize in government affairs, international affairs, regulatory matters, trade, product stewardship, toxicology and EH&S, among others.

Registration

As a speaker, your registration for the webinar series is free. ACC Meeting Services will manage your registration on your behalf and you are welcome to participate in any other session offered during the series at no cost.

Bios & Headshot

Speakers are asked to submit a brief bio and a headshot that will be used to promote the webinar on [HYPERLINK "http://www.globalchem.org"]. Professional/social networking info may also be submitted (e.g., LinkedIn, Twitter).

Webinar Presentation Tips

- Virtual events rely heavily on keeping the audience's attention. If possible, powerpoint slides should be kept to a minimum. **The focus of any presentation should be the speaker and the content given, not the slides.** Be mindful of your presentation length and slide legibility. Avoid text-heavy slides and use large font sizes. Due to the nature of the virtual event, screen space is limited, and any graphics should be easily visible and compelling for attendees.

- Build in **5** minutes at the end of your presentation session for a question and answer period. If part of a panel discussion, your facilitator will assist you in opening this dialogue after all presenters have spoken.

- ACC reserves the right to contact speakers if we determine that any edits to presentation materials are necessary. While speakers are free to use their own PPT templates, it is recommended that you have a legal review performed with your internal attorney(s) prior to submitting it for the webinar.

GLOBALCHEM

Webinar Series

Intent to Record Webinar:

ACC intends to record each session of the 2020 GlobalChem Webinar Series for later viewing. The recorded sessions may capture PowerPoint presentation slides and audio of moderators and presenters, and/or still photographs of moderators and presenters.

ACC requests that moderators and presenters agree to be identified by name and that their materials may be included in the recording. Presenters may request that specific material be withheld, or that their material or audio not be included in the final recording.

The recordings in no way restrict the publication or dissemination of any material in any form by moderators or presenters, or others authorized by moderators or presenters.

General Technology Tips

ACC recognizes the challenges we are all facing as we weather the COVID-19 storm. Here are a few tips on technology that will facilitate a successful webinar:

- Optimize Your Home Network
  - When possible, plug directly into your router for a hardwired connection.
  - If on W-Fi, access your network's 5G band vs. the standard 2.4G.
  - The ideal distance from your router is 5-8 feet to achieve the strongest wireless signal.
  - Minimize network traffic by limiting family members' usage of streaming services or other video conferencing tools during your session.

- Camera & Background
  - Maintain a neutral background with minimal distractions.
  - Avoid any light source BEHIND you such as a lamp or window with the sun shining through. This causes some cameras to adjust its exposure settings and could lead to a dark picture.
  - Maintain a good ratio of headspace vs. background space.

- Microphone
  - When possible, use a dedicated, hardwired headset for the best audio results.

- Connectivity Issues
  - If you experience a temporary lack of connectivity, simply try to reconnect while your moderator fills in for you.
  - If your connectivity issue is more severe, dial into the audio only portion of the webinar to continue participating without video. Having a printed out version of your talk and slides in advance is helpful.

GLOBALCHEM

Webinar Series

Your Participation

- Session: **TSCA New Chemicals**
  This webinar will address key changes in the section 5 program, and challenges faced by EPA and submitters, including information requirements, assessment of risks, and practical tips.

- Date & Time: **Wednesday, May 13, 2020, 12:00-1:30 PM**
  Please log into the webinar no later than 11:30 am

  - **WEBEX URL:** [HYPERLINK
    Ex. 6 Personal Privacy (PP) - conference code/call in number
    EVENT PASSWORD: Ex. 6 Personal Privacy (PP) - conference code/call in number
  - **Audio Only Dial In:** Ex. 6 Personal Privacy (PP) - conference code/call in number
    Access Code: Ex. 6 Personal Privacy (PP) - conference code/call in number

- Pre-Webinar Group Dry Run: **Monday, May 11, 12:00-12:30 PM**
  - Please use the same login link above to join this practice session. During this time, we will go over the flow of the webinar, confirm video and audio capabilities and answer any question you may have.

- Session Organizer: **Mike Walls, ACC**

- Moderator: **Mike Walls, ACC**

- Speakers:
  - **Lynn Dekleva, U.S. EPA**
  - **Rich Engler, Bergeson & Campbell**
  - **EPA?**
  - **EPA?**

- Webinar Format:
  (Adjust as necessary by Organizer or Moderator)

  - **12:00 – Welcome & Housekeeping Items by Schubert Fabros**
  - **12:05 – Housekeeping & Opening Remarks from Mike Walls & Introduction of Panel**
  - **12:10 – Lynn Dekelva Remarks with PPT**
  - **12:25 – Other EPA speakers**
  - **12:50 – Rich Engler Remarks with PPT**
  - **1:05 – Short Roundtable Discussion from Panel [?], Moderated by Mike Walls**
  - **1:10 – Q&A Session from Audience (curated by Kat Gale)**
  - **1:30 – Closing & Thank You**

Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 4/29/2020 3:00:42 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: Re: Invitation to "headline" May 13 ACC GlobalChem Webinar on New Chemicals

Thank you Lynn! I'll look forward to talking to you. Mike

Sent from my iPhone

On Apr 29, 2020, at 10:45 AM, Dekleva, Lynn <dekleva.lynn@epa.gov> wrote:

> Mike,
> I'd be glad to participate. I'll give you a call to discuss potential options sometime today or tomorrow morning.
> Hope you and your family are surviving and thriving in this unusual time.
> Regards,
> Lynn
>
> Lynn Dekleva, Ph.D.
> Associate Deputy Assistant Administrator for New Chemicals
> Office of Chemical Safety and Pollution Prevention
> U.S. Environmental Protection Agency
> 1201 Constitution Ave., NW
> Washington, DC 20460
> (202) 564-3895
> (202) 845-6261 (cell)
> dekleva.lynn@epa.gov
>
> **From:** Walls, Michael <Michael_Walls@americanchemistry.com>
> **Sent:** Tuesday, April 28, 2020 10:47 AM
> **To:** Dekleva, Lynn <dekleva.lynn@epa.gov>
> **Cc:** Gale, Kat <Kat_Gale@americanchemistry.com>; Pierce, Alison <Pierce.Alison@epa.gov>
> **Subject:** Invitation to "headline" May 13 ACC GlobalChem Webinar on New Chemicals
>
> Lynn, I hope you and your family are all doing well. I look forward to the day when we are back to at least "near-normal"!
>
> As you know, ACC cancelled GlobalChem 2020 due to the pandemic. In its place, we have scheduled a series of webinars that we are calling the "GlobalChem 2020 Webinar Series." The webinars are being held each Wednesday beginning April 29, for 90 minute sessions beginning at 12 noon eastern. We very much appreciate the willingness of so many of the EPA staff to join our panels in these webinars.
>
> We have tentatively scheduled Wednesday, May 13 for a session on the New Chemicals program, and I would like to formally invite you to provide the opening presentation/remarks at the session. You have been working hard to establish many process changes and efficiencies, and I know our audience would appreciate having your perspective on those changes and how submitters can provide the Agency the information it needs to make decisions on new chemicals.

I will be moderating the session. I thought that with you and perhaps one or two others from the new chemicals staff, we could have a robust discussion of the program and how it has changed since June, 2016, including the significant improvements in the average time to make decisions on submissions. As we were planning the original GlobalChem workshop session on new chemicals, we had a list of some six other EPA staff to include, and we would appreciate your input on who else we might invite. Rich Engler of Bergeson & Campbell is our fourth speaker, and he will provide a private sector perspective on the changes. In general, I think the session can address key changes in the section 5 program, and challenges faced by EPA and submitters, including information requirements, assessment of risks, and practical tips.

With four speakers, we could have up to 15 minutes from each speaker, and then provide an opportunity for questions and answers. The webinars will be moderated by WebEx, so that everyone will be muted during the presentations and we can manage Q&A appropriately. We don't need extensive slide presentations, but I know the audience at GlobalChem has always appreciated having material that they can later reference. My hope would be that we could schedule a quick call for all the speakers to coordinate presentations.

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I hope you will be able to join us as our headline speaker on May 13. I look forward to hearing from you. If you would prefer to speak directly, my cell number is Ex. 6 Personal Privacy (PP) - personal phone Thank you for your consideration! Regards, Mike

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Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 4/28/2020 2:47:06 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
CC: Gale, Kat [Kat_Gale@americanchemistry.com]; Pierce, Alison [Pierce.Alison@epa.gov]
Subject: Invitation to "headline" May 13 ACC GlobalChem Webinar on New Chemicals

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email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 8/30/2019 3:09:01 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: RE: Accessing pre-CDX PMN files

Lynn, after I sent this message I became aware that EPA already has information on the website on accessing those old files. Sorry I did not check that before, and sorry to bother you.

Take care. Mike

From: Walls, Michael
Sent: Friday, August 30, 2019 10:52 AM
To: 'dekleva.lynn@epa.gov' <dekleva.lynn@epa.gov>
Subject: Accessing pre-CDX PMN files

Lynn, an ACC member company has a number of files that were created using the TSCA PMN generation and EPA submission software that was available before CDX became the standard. Unfortunately, the software doesn't seem to be available anymore, and they cannot open those files. These are files with extensions like filename.sup_tsca and filename.pmn_tsca.

Does EPA still provide access to the pre-CDX software, or know how companies could get the software? I imagine this might be an issue for a number of companies where prior submitted information could be relevant for current section 5 submissions.

Thanks very much for your help with this question. I hope you have a great Labor Day weekend – looks like the weather will be great for some rowing! Mike

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Message

From: Walls, Michael [Michael_Walls@americanchemistry.com]
Sent: 8/30/2019 2:51:54 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: Accessing pre-CDX PMN files

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 6/10/2019 11:16:23 AM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
CC: Dunn, Alexandra [dunn.alexandra@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: TSCA Consent Order Document
Attachments: 00272428.pdf

Lynn,

Appended is a summary of our thoughts on suggested changes to the notification review process and standard TSCA Consent Order.

We look forward to your thoughts.

Lynn

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

MEMORANDUM

Via E-Mail

DATE: June 10, 2019

TO: Interested Parties

FROM: Bergeson & Campbell, P.C.

RE: Consent Order Challenges

The proposed changes in the text of a standard U.S. Environmental Protection Agency (EPA) consent order (or unilateral order) under the Toxic Substances Control Act (TSCA) that we have reviewed may lead to enhanced efficiency in certain limited respects. We recognize, however, that converting an offered consent order to a unilateral order after some fixed amount of time may put EPA in a difficult legal and challenging optical position. From our perspective, many of the delays that the changes are intended to address are amenable to resolution by focusing on the front end of the process, as the delays often arise from EPA's inability efficiently and accurately to review premanufacture notifications (PMN) and to develop a robust, defensible assessment and regulatory outcome.

To address avoidable delays in the New Chemicals Program, the Office of Pollution Prevention and Toxics (OPPT) may wish to focus on the sources of those delays and offer potential solutions. In our view, OPPT is not currently in a position to force a submitter to choose between a unilateral order and possibly resorting to judicial review, or withdrawing the PMN and potentially paying an additional PMN fee.

Below we identify sources of delays and offer suggestions on how OPPT and submitters can work to reduce them.

Sources of Delay

Errors in Risk Assessment

Engineering Report: Example: Engineers used the submitter's release amount from container cleaning but wrongly increased the number of release days 40-fold. As a result, the Risk Assessment Division (RAD) estimated that 50 percent of the annual production volume was being discarded during processing.

Suggested solution: Include in the report QC a step to consider the "reasonability" of the assessment. This step would ensure that total release amounts when back-

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ED_005294A_00000186-00001

calculated to compare to production volume are determined to be reasonable. To help develop this process, submitters could be encouraged to conduct their own "reasonability" assessments and inform EPA when issues are identified.

Heath Report: Example: assessors routinely use no-effect levels (NOEL) rather than no-adverse effect levels (NOAEL).

Suggested solution: Encourage submitters to provide an interpretation along with the study report. If RAD assessors reject a submitter's interpretation, RAD would be required to provide a written response explaining the basis for selecting the NOEL over the NOAEL and why the selection of an NOEL would be qualified as "best available science" for TSCA purposes.

Poor Analog Choices: Example: Inorganic substances with very different metals and organic substances with different functional groups or substantial differences in physical chemical properties.

Suggested solution: Encourage collaboration between hazard assessors and chemists and consider including an "analog qualification step" where hazard assessors and chemists discuss and qualify analogs. In some cases this would be *pro forma* (slight difference in chain length), but it would nonetheless be useful to ensure that the process for selecting analogs is consistent and predictable and that OPPT agrees internally that analogs are qualified. This would also be an area that senior OPPT leadership could focus their review of a case and OPPT staff would explain why the choice recommended is scientifically sound (*i.e.,* represents best available science). If an analog is claimed as confidential business information (CBI), the assessor would include information in their report about the similarities/differences to provide minimal transparency, *i.e.,* physical chemical aspects. If an analog choice cannot be scientifically justified, OPPT should consider the appropriateness of an "insufficient information" determination.

Insufficient Release and Exposure Information

Submitter-controlled sites: Example: Submitters neglect to provide details about frequency of equipment cleaning, cleaning agent used (solvent or water), and disposition of rinsate. Important information about releases and exposures at submitter-controlled sites is not required on the PMN form.

Suggested solution: Include the need for this information in OPPT's Points to Consider document and Sustainable Futures training. Additionally, OPPT could conduct outreach to industry associations and other stakeholders about the need for and importance of such information. Long-term, this could be included in an amended PMN form.

Sites controlled by others: Example: Submitter may not know procedures used by customers or others farther down in the supply chain. Information about releases and exposures at processing and use sites is not required on the PMN form.

Suggested solution: OPPT may wish to conduct outreach and education with industry associations and other stakeholders focusing on opportunities for joint submissions. If the needed information is relevant to the determination, the issue should be raised and discussed in the post-Focus process. Long-term, this could be included in an amended PMN form.

OPPT Rejecting Information Contained in the Submission

OPPT often relies upon conservative assumptions in preference to information submitted in notice. This is especially frustrating to submitters who devoted the effort, time, and expense required to gather and describe, with specificity, the conditions of use (COU) throughout the supply chain. This RAD practice directly conflicts with OPPT's Points to Consider guidance to provide details of COU throughout the supply chain. Presently, submitters provide details but derive little or no benefit in doing so.

Suggested solution: OPPT should develop and communicate a policy that factual information, based on test data, knowledge, experience, or industry standard practice, when accompanied by explanations of its relevance to the case, and why it is believed to represent best available science, will be utilized by OPPT assessors when determined to be appropriate in preference to modelled or assumed values as representing the best available science. OPPT has the discretion to reject such information when deemed appropriate, provided the notifier is informed of OPPT's concerns and the scientific and/or legal basis (*i.e.*, why it does not represent best available science). OPPT should provide guidance on what is necessary to persuade assessors that submitter information is justifiable over conservative models, both in the Points to Consider guidance document and in comments related to the specific submission. Currently, minimal justification is provided by RAD and generally is no more than the "RAD model is more conservative." If RAD will always choose the more conservative information between what is submitted and what RAD models predict, there is no incentive for submitters to provide any COU information in the submission.

OPPT uses inappropriate industry code (SIC) in models. Example: RAD used "electronics manufacturing" instead of "pulp and paper" for a product used in that industry. SIC codes lead to the selection of the release and exposure scenarios. Often SIC codes do not match the uses specified in the submission without explanation.

Suggested solution: In the Points to Consider guidance document, OPPT may wish to provide a list of SIC codes used in models, so submitters can suggest best matches in a submission. If RAD uses other codes, RAD would either specifically discuss these issues in the

post-Focus meeting (*see* next section) with the notifier or provide a written justification and basis for selecting other SIC codes.

Optimizing Pre-notice Meetings

OPPT management properly emphasizes the value of pre-notice consultation to industry stakeholders. Often, however, the utility of such meetings is questionable. Submitters often develop complete draft PMNs, but EPA staff lack the bandwidth to review the draft PMN and often attend meetings having only given a cursory glance at the submitted information and thus are ill-prepared to respond substantively to important submitter questions. Frequently, written questions go unanswered for months. Pre-notice reviewers are not necessarily the same reviewers assigned to the PMN once it has been submitted. Feedback from most pre-notice meetings is too often of limited value and consists of suggestions such as "submit as much information as you can" -- the same advice found in the Points to Consider guidance document.

Suggested solution: Instead of or in addition to pre-notice meetings, OPPT could consider adding a new step that occurs promptly after Focus. OPPT could offer to hold post-Focus meetings with notifiers to discuss the details of the risk evaluation in a practical and focused way, and one that, if applied consistently, would contribute much "learning by doing" for both EPA and submitters and would improve the PMN review process. EPA would bring its technical and regulatory staff working the case to the discussion, as would the notifier, so all relevant issues and concerns can be discussed. Such a step would provide a significant transparency boost to OPPT's assessment process that, while initially challenging, would improve over time and help provide an efficient and valuable forum for clarifying EPA's concerns and issues at an early stage in the process. In keeping with the concept of "applicable review period," this could be required to be held within a week or two after Focus. The results of the discussion could be captured and reported in a post-Focus report prepared by the review team that becomes part of OPPT's record of the case and that should be provided to the notifier. There may be value in appointing senior OPPT staff (likely technical staff since the focus is the assessment, not the regulatory approach) who would chair such post-Focus meetings (like a Structure Activity Team (SAT) or Focus chair). This would have the added benefit of bringing consistency to the process and making an arbiter available in the meeting who might be able to resolve issues directly or to take issues back for future resolution. The chair would also review/approve the report of the meeting prepared by the OPPT review team.

A key benefit of the suggested approach is that EPA's new chemicals team would have reviewed the case in detail and would, at that point, know better what information is needed to address any concerns and could provide specific, targeted feedback to the submitter. If the post-Focus meetings were scheduled and convened promptly after Focus, this would help bring issues and cases to prompt closure consistent with the concept of the applicable review period.

This solution does not address delays in timing *per se*, but it could lessen the frustration of pre-notice communication that contributes to delays and increases work loads for submitters and EPA staff. As the new paradigm matures and EPA is able to provide more specificity as to what submitters need to provide to convince RAD to use submitter information *in lieu* of standard model assumptions, post-Focus meetings could revert back to pre-notice. Post-Focus meetings could also help identify and promptly resolve errors in assessments, whether the errors were in what the submitter provided or introduced in EPA's assessment.

Pre-notice communication may still be valuable, but should be limited to specific, narrow questions, such as "Will EPA consider substance X as a read-across candidate for new chemical Y?" OPPT response time should be tracked and, if responses cannot be provided in a timely manner, OPPT should stop emphasizing pre-notice communication as an option.

Submitters are Slow to Reply in Post-Focus Phase

Submitters may struggle to understand how EPA came to a decision to regulate and/or how to refute such a conclusion. OPPT should, in all cases with a post-Focus regulatory outcome, send the full suite of new chemical reports (or at a minimum, engineering, exposure, and SAT reports) to the notifier in preparation for the post-Focus meeting. During the post-Focus meeting, OPPT should also identify, discuss, and characterize the basis of the hazard issues identified, the key releases, and the exposures of concern and measures the submitter could consider taking to address those concerns. There are few TSCA practitioners who can properly interpret these arcane reports. Until OPPT resumes its Sustainable Futures training, OPPT could assist submitters by highlighting its concerns and pointing out the key hazard, release, and exposure findings that led to the regulatory outcome.

Submitters struggle to develop information to refute EPA's assessment. Challenges include identifying information about downstream COU, disposal methods, and hazard data that may assist EPA with its assessment. Delays may be exceptionally long if the submitter is developing information through testing (*e.g.*, toxicity testing or exposure monitoring).

Suggested solution: Post-Focus meetings could help bring clarity to submitters as they struggle to understand OPPT's concerns and provide an opportunity for the submitter and OPPT to discuss what information is needed and when such information might be available.

Delays in Implementing Regulatory Outcomes

Delays in EPA issuing consent orders. Once EPA and a submitter agree on a risk determination that includes a regulatory outcome, there are significant delays in EPA issuing

a consent order. Not surprisingly, consent orders require significant company review by multiple layers of management.

Suggested solution: Streamline consent orders along the lines discussed. Streamlining consent orders could be accomplished in several ways: put case-specific information in appendices; eliminate unnecessary boilerplate (*e.g.*, provisions that duplicate requirements already specified in 40 C.F.R. Subchapter R[1]); and eliminate redundant provisions that have accumulated over the years. There is a possible "advance notice" issue with the boilerplate, so perhaps EPA should send the proposed boilerplate language, including the choices made by EPA when language options are included in the boilerplate, to the notifier for a 30-day review period that should occur promptly after the post-Focus meeting if EPA's regulatory concerns have not been resolved. This would provide notice of the proposed boilerplate language and any further review by the notifier could be limited to the case-specific aspects memorialized in the appendices. In the event that EPA made changes in the final boilerplate provisions that were compared to the proposed boilerplate provided for the 30-day review, EPA would highlight these changes in a redline version; such redline changes might also be open for discussion. OPPT should maintain statistics on this process with periodic reporting to management that would include a discussion of significant issues identified in boilerplate language along with proposed/applied solutions. This practice could serve as a useful "management of change" tool and track information helpful to TSCA stakeholders.

Delays in submitter response to proposed orders. Although we are neither aware of nor have experienced this issue, we understand from OPPT that submitters may be hesitant to sign consent orders and, as a result, issues remain unaddressed for long periods of time. We do see a pattern of clients being reluctant to sign a consent order, but understand OPPT wishes not to engage in protracted phone tag with unresponsive submitters.

Suggested solution: If a submitter does not respond in ten business days after receipt of a consent order, OPPT could promptly schedule a conference call to discuss submitter's issues and reluctance. The call would be held within an additional seven to ten days. This process should also be tracked and statistics reported periodically to management.

Delays in issuing "based on" SNURs. OPPT currently has no timeline for proposing "based on" SNURs. The delay between an initial determination and a SNUR proposal can easily be a year or so.

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[1] Bergeson & Campbell, P.C. (B&C®) sees value in including an appendix that informs the notifier of obligations that are triggered by the consent order, such as TSCA Section 12(b) export notices.

Suggested solution: Such SNURs essentially become part of the PMN's applicable review period and should accordingly be held to a measurable timeliness standard. Either propose such a SNUR in a timely manner (management should establish a standard timeframe related to the concept of applicable review period, *e.g.*, proposed SNUR signed within 45 days of OPPT making such a decision) or rely upon orders. This should also be tracked and reported periodically to management.

The Market Reacts Negatively to Consent Orders and SNURs

Some companies, especially companies that are not TSCA manufacturers and less familiar with the requirements, are often reluctant to purchase SNURed substances. A company may assume that the regulated substance is more dangerous than an existing chemical counter-part that does not have a SNUR.

Suggested solutions: Manufacturers, distributors, and downstream trade associations need to do more to educate customers and their members, respectively, regarding what the regulations mean and how customers can comply. Manufacturer and distributor trade associations should also be engaged as appropriate and develop and disseminate educational materials. OPPT can also provide more guidance. For example, with respect to 40 C.F.R. Section 721.125(c), OPPT could provide guidance along the lines of "[s]tandard business records, such as sales records, or invoices, that capture the name and address of the recipient, the date of transfer, and the quantity sold or transferred [which] are likely sufficient to satisfy this requirement." Hearing from EPA that records now generated in the normal course of business can be used to satisfy TSCA recordkeeping requirements in this regard could help reduce SNUR resistance.

EPA Needs to Value Risk-Related Pollution Prevention (P2)/Green Chemistry Benefits

Historically, from at least the inception of the Pollution Prevention Act of 1990, EPA considered and valued P2 and green chemistry benefits when considering the need for and nature of risk management steps on new chemicals under old TSCA. While amended TSCA has changed the role of non-risk factors in reviewing and regulating PMNs, OPPT is not precluded from considering relative risk benefits that can be achieved through careful consideration and application of P2 and green chemistry approaches.

Suggested solutions: As elaborated in the attached document, we believe there are strong arguments to be made that OPPT resume considering relative risk-related P2/green chemistry benefits in its risk management strategies. Such a step would offer additional incentive to industry to green its new chemical product offerings while making clear the value that EPA places on such improvements in new chemicals.

Lack of Transparency Regarding Source of Delays

Voluntary suspensions are requested by both submitters and EPA. EPA delays will continue to be a significant problem until new staff is on-boarded and trained and OPPT policies and procedures settle into a more predictable routine. The ultimate goal is for OPPT to review PMNs and develop a thoughtful pre-notice communication strategy. EPA does not yet seem to have the bandwidth for robust pre-notice communication or to provide clarity as to what information is necessary to "override" standard assumptions.

Suggested solution: Without rulemaking, OPPT can differentiate between submitter-requested suspensions and EPA-requested suspensions by having submitters request delays through written (*i.e.*, submitted through the Central Data Exchange (CDX)) suspensions with specific target dates for the information to be developed and submitted. EPA suspensions can continue to be addressed by phone calls, with the program manager recording both that a suspension was requested and where the case is within EPA's review and action (*e.g.*, issuing a consent order or proposing a SNUR) processes. These suspensions should be distinguished and tracked and suspension statistics periodically reported to management with an eye towards identifying problems, issues, and solutions. The absence of any metrics on either side regarding who (submitter or EPA) causes more delay hampers EPA's ability to identify root causes and potential solutions to the delay problem.

* * * * *

We hope this information is helpful. As always, please call if you have any questions.

Attachment

TSCA
NEW CHEMICALS
COALITION

White Paper: Consideration of "Nonrisk" Versus "Risk" Factors Under Toxic Substances Control Act Section 5

March 22, 2019

Introduction

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), "unreasonable risk" is to be determined "without consideration of costs or other nonrisk factors," (referred to as the "'without consideration' phrase" in this paper). This amended language appears in TSCA Sections 5, 6, 9, and 21; interestingly, it does not appear in Section 4. This paper explores the application of the term "nonrisk factors" to new chemical determinations and regulatory actions under Section 5.

Legislative History

The term "nonrisk factors" appears to have been introduced as an amendment to the Senate bill, S. 697, by Senator Jim Inhofe (R-OK) in 2015[1] where the term appeared in the definition of "safety standard" at Section 3(16), and remained in the bill when the Senate passed S. 697 by unanimous consent in December 2015.[2] The term was retained in the compromise text between the House and Senate in May 2016,[3] although its usage was somewhat different. The compromise text did not retain the Section 3 definition of safety standard and the "without consideration" phrase generally appeared in the context of the U.S. Environmental Protection Agency (EPA) assessing chemical risks (Sections 9 and 21) and specifically regarding conducting a risk evaluation to determine unreasonable risk under Section 6(b). The phrase was also included in Section 5(a)(3)(B)(ii)(I) concerning reviewing and making a determination on a new chemical and in Section 5(e) of amended TSCA concerning regulatory actions to prohibit or limit commercial activities "to the extent necessary to protect against an unreasonable risk."

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1 Available at https://www.gpo.gov/fdsys/pkg/BILLS-114s697rs/pdf/BILLS-114s697rs.pdf.

2 Available at https://www.epw.senate.gov/public/_cache/files/e56cfb54-bef6-4625-ba0d-590af2a40c73/s.697---inhofe-substitute---10-21-15-.pdf.

3 TSCA Reform -- Compromise Text, available at https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160520TSCASummary.pdf.

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: 202-557-3801 | F: 202-557-3836

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Discussion of Role of "Risk" Versus "Nonrisk" Factors in TSCA Section 5

Within this section there are three references to "unreasonable risk" and all include the "without consideration" phrase that includes the term "nonrisk factors." The first is at Section 5(a)(3)(B)(ii)(I) and pertains to the EPA review and determination that a new chemical "may present an unreasonable risk." The latter references appear in Section 5(e). The first of these is in Section 5(e)(1)(A)(ii)(I) and essentially cross references the determination of "may present an unreasonable risk" made under Section 5(a)(3)(B)(ii)(I), while the second reference pertains to the "extent necessary" consideration in imposing an order under Section 5(e). While these references can be read as disallowing consideration of "costs or other nonrisk factors" in making a determination or in imposing an order, they cannot be interpreted as disallowing consideration of "risk factors."

EPA, however, appears to be interpreting "nonrisk factors" as precluding consideration of *any factors* beyond the risk *per se* of the notified new chemical in isolation in making its determination of unreasonable risk or issuing an order to the extent necessary to protect against the unreasonable risk. By doing so, EPA goes beyond the text and, as a matter of policy, restricts its ability to weigh "risk factors" such as the potential risk of the new chemical compared to the risk of an existing chemical that the new chemical is intended to replace. This policy position, beyond clearly exceeding the statutory text, presents a variety of disincentives and challenges to a new chemical innovator looking to market a safer, greener replacement chemical. While the new chemical may not be risk-free, it could be relatively or even far safer than the incumbent, existing chemical when the panoply of risk factors such as toxicity, exposure potential, persistence, bioaccumulation, release, susceptibility to treatment, and others are considered. Such risk factors can take the form of pollution prevention benefits (lower toxicity, lower potential for releases and exposures, and less persistence in the environment), energy efficiency (reduced contribution to global warming; lower operating temperatures and pressures that contribute to worker safety) or process efficiency (lesser amounts needed to achieve similar or superior performance with resultant lower material needs and lower exposure potential), or provide other positive risk attributes relative to the existing chemical products.

As a matter of law and as part of an overall goal of safety, EPA should be including such risk-based comparisons as part of its determination as well as part of its decision to take "extent necessary" actions under Section 5(e). Prior to the passage of Lautenberg, EPA did include relative risk considerations in its decisions about premanufacture notices (PMN) but, at the moment, this does not appear to be occurring. In addition, by avoiding consideration of a risk

comparison of the new chemical with the existing chemical, EPA is imposing barriers to technological innovation, which is contrary to TSCA's policy statement at Section 2(b)(3).

Most "new chemical" products are not entirely new but are chiefly intended to improve on the functionality and performance of existing chemicals by commercializing new chemicals that are more efficient, have better processing options, have better performance, and are less toxic. The net result of these factors is strong continuous improvement. Increased efficiency in manufacturing, processing, and use also translates into less material being used and less material being released into the environment, which is the very essence of pollution prevention. The availability of better processing options, including equal or improved performance at lower temperatures, leads to reduced energy usage and potentially safer work environments. These are goals TSCA was intended to achieve, and represent what EPA should be attempting to support and encourage as part of the Section 5 chemical review process. In fact, many of the risk-based factors discussed above are directly relatable to, if not the same as, the considerations brought to bear in applying the Sustainable Futures program tools to new chemicals and are referenced within EPA's own definition of green chemistry.[4]

Discussion/Proposal

It is not clear to us why there is a question about the applicability of risk factors in making determinations and in considering and taking regulatory action on new chemicals. EPA is urged to consider carefully the text in Section 5 and to clarify the role of the elements that relate to a comparison of risks between new and existing chemical alternatives and to confirm that such a comparison is not precluded as a "nonrisk factor." In our view, such comparisons are within the scope of what can and should be considered by innovators when developing new chemicals and by EPA in its "may present" determinations and in consideration of "extent necessary" in taking action to control new chemicals. If a new chemical submitter provides relevant information in the Pollution Prevention (P2) section of the PMN, including information based on Sustainable Futures tools, EPA should have a systematic approach to consider that information and include these as risk-based factors in its decisions under Section 5. Indeed, if information is provided as to how the new chemical represents a risk-based improvement relative to an existing chemical, EPA's determination of potential risk for that new chemical should include consideration of

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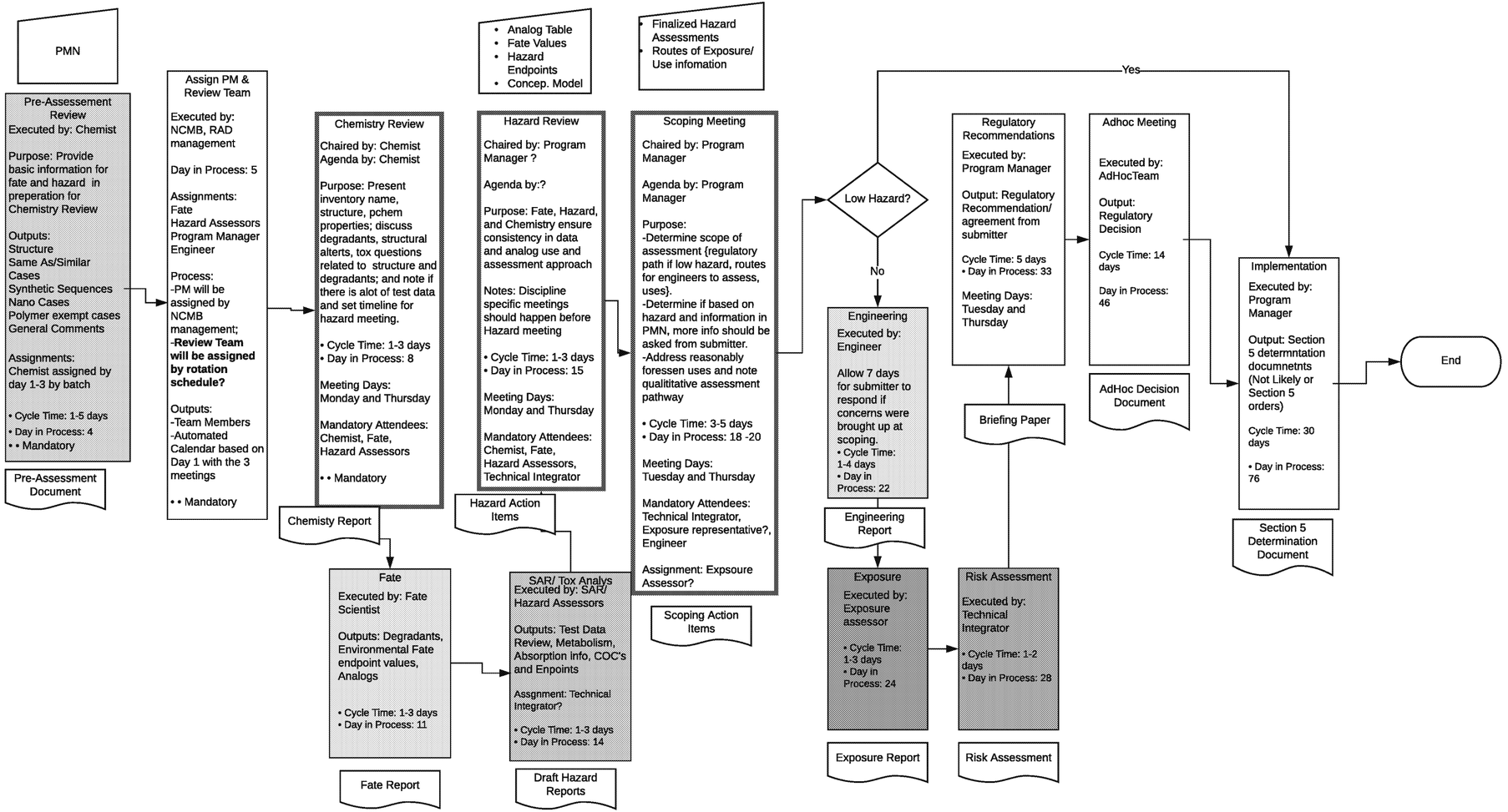
4 EPA, Basics of Green Chemistry, Definition of green chemistry, available at https://www.epa.gov/greenchemistry/basics-green-chemistry#definition.

potential risk if the new chemical does not proceed to or is disadvantaged in the market, and the existing chemical remains.

We urge EPA promptly to consider the points raised in this paper. We believe there are strong arguments that EPA is not barred from, rather, it is required to consider risk-based factors in making determinations under Section 5(a)(3)(B)(ii)(I) and in taking regulatory decisions under Section 5(e). Further, assuming that EPA agrees with the conclusions offered, we urge prompt action to communicate this understanding to stakeholders. This should include encouraging notifiers of new chemicals that are still in review, including those in voluntary suspension, to develop and submit information regarding risk-based factors for EPA's consideration, and the development of EPA guidance for use by future notifiers. We believe that the existing guidance for Sustainable Futures and for the voluntary Pollution Prevention (P2) page provides an excellent start for such an effort.


PMN
Pre-Assessement Review
Executed by: Chemist
Purpose: Provide basic information for fate and hazard in preperation for Chemistry Review
Outputs:
Structure
Same As/Similar Cases
Synthetic Sequences
Nano Cases
Polymer exempt cases
General Comments
Assignments:
Chemist assigned by day 1-3 by batch
• Cycle Time: 1-5 days
• Day in Process: 4
• • Mandatory
Pre-Assessment Document
Assign PM & Review Team
Executed by: NCMB, RAD management
Day in Process: 5
Assignments:
Fate
Hazard Assessors
Program Manager
Engineer
Process:
-PM will be assigned by NCMB management;
-Review Team will be assigned by rotation schedule?
Outputs:
-Team Members
-Automated Calendar based on Day 1 with the 3 meetings
• • Mandatory
Chemistry Review
Chaired by: Chemist
Agenda by: Chemist
Purpose: Present inventory name, structure, pchem properties; discuss degradants, structural alterts, tox questions related to structure and degradants; and note if there is alot of test data and set timeline for hazard meeting.
• Cycle Time: 1-3 days
• Day in Process: 8
Meeting Days:
Monday and Thursday
Mandatory Attendees:
Chemist, Fate, Hazard Assessors
• • Mandatory
Chemisty Report
Analog Table
Fate Values
Hazard Endpoints
Concep. Model
Hazard Review
Chaired by: Program Manager ?
Agenda by:?
Purpose: Fate, Hazard, and Chemistry ensure consistency in data and analog use and assessment approach
Notes: Discipline specific meetings should happen before Hazard meeting
• Cycle Time: 1-3 days
• Day in Process: 15
Meeting Days:
Monday and Thursday
Mandatory Attendees:
Chemist, Fate, Hazard Assessors, Technical Integrator
Hazard Action Items
Finalized Hazard Assessments
Routes of Exposure/ Use infomation
Scoping Meeting
Chaired by: Program Manager
Agenda by: Program Manager
Purpose:
-Determine scope of assessment {regulatory path if low hazard, routes for engineers to assess, uses}.
-Determine if based on hazard and information in PMN, more info should be asked from submitter.
-Address reasonably foressen uses and note qualititative assessment pathway
• Cycle Time: 3-5 days
• Day in Process: 18 -20
Meeting Days:
Tuesday and Thursday
Mandatory Attendees:
Technical Integrator, Exposure representative?, Engineer
Assignment: Expsoure Assessor?
Scoping Action Items
Fate
Executed by: Fate Scientist
Outputs: Degradants, Environmental Fate endpoint values, Analogs
• Cycle Time: 1-3 days
• Day in Process: 11
Fate Report
SAR/ Tox Analys
Executed by: SAR/ Hazard Assessors
Outputs: Test Data Review, Metabolism, Absorption info, COC's and Enpoints
Assgnment: Technical Integrator?
• Cycle Time: 1-3 days
• Day in Process: 14
Draft Hazard Reports
Low Hazard?
No
Yes
Engineering
Executed by: Engineer
Allow 7 days for submitter to respond if concerns were brought up at scoping.
• Cycle Time: 1-4 days
• Day in Process: 22
Engineering Report
Exposure
Executed by: Exposure assessor
• Cycle Time: 1-3 days
• Day in Process: 24
Exposure Report
Risk Assessment
Executed by: Technical Integrator
• Cycle Time: 1-2 days
• Day in Process: 28
Risk Assessment
Briefing Paper
Regulatory Recommendations
Executed by: Program Manager
Output: Regulatory Recommendation/ agreement from submitter
Cycle Time: 5 days
• Day in Process: 33
Meeting Days:
Tuesday and Thursday
Adhoc Meeting
Executed by: AdHocTeam
Output: Regulatory Decision
Cycle Time: 14 days
Day in Process: 46
AdHoc Decision Document
Implementation
Executed by: Program Manager
Output: Section 5 determntation documnetnts (Not Likely or Section 5 orders)
Cycle Time: 30 days
• Day in Process: 76
Section 5 Determination Document
End

Chemistry Meeting Standard Work

Chemist presents

- Structure, P-Chem, Analog, and SMILES-SMARTS

Team Discussion

- Degradants/ Metabolites
- Structural Alerts/ Chemical Categories

  This includes discussion on whether structural alert is applicable (bioavailability, water solubility, etc.)

- Eco (questions on structure and degradants of concern)
- Health (questions on structure and degradants of concern)

  For example: does the new chemical substance degrade in neutral or acid pH?; if the new chemical substance hydrolyzes, what is the rate of hydrolysis?; for a polymer, what is the composition of the chemicals under 1,000 MW
- Use (if SNUR, what is the new use)
- Reasonably Foreseen uses (same as cases, patents, etc.)

For timeline to Hazard Meeting

- Test Data in PMN/ missing data (example if guideline noted in SDS)

  (if SNUR, was data looked at previously)

Note: This is a checklist of what to discuss at the meeting. You do not need to fill this out.

STANDARD WORK

Hazard Meeting

Date:
Time:
Room:

Required Documents: Table with identified analogs, Fate Report, SAR/Tox Analysis, Information from models, Regulatory History, Conceptual Engineering Model

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P-xx-xxxx

Chemical Categories /Structural Alerts
Eco
Human Health

Human Health: Absorption

Metabolism & Degradation (Fate Assessor):
Eco
Health

PMN/Same As Data:
Chemistry
Fate
Eco
Human Health

Analog Data
Fate
Eco
Human Health

COCs/ Endpoints of Concern
Eco
Human Health

Routes of Exposure of Concern:

Action Items:

Note: This is a checklist of what to discuss at the meeting. You do not need to fill this out.

STANDARD WORK

Scoping Meeting

Date:
Time:
Room:

Required Documents:	Finalized Eco and Human Health Hazard Reports, Conceptual Engineering Model
Outputs:	Determine Assessment & Regulatory Path

Case no:
Company:.
Chemical Name:
Uses:
Production Volume:

Endpoints of Concern
Eco
Acute
Chronic

Human Health

Releases and Routes of Exposure based on the Conceptual Model

Releases (Gen Pop)
Workers

Foreseeable Uses/ Consumer Uses

Reasonably Foreseen Uses

Risk approach/ Regulatory Path

Action Items and Deadlines

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
[IF DocVariable MonthStart \@ dddd = "Sunday" 1 ""]	1 PMN comes in	2	3 Pre-Assessment Doc	4	5	6
7	8 Chemistry Meeting	9	10	11 Analog table	12	13
14	15 Hazard Meeting	16	17	18 Scoping meeting	19	20
21	22	23	24	25	26	27
28	29	30 CCD Options Meeting		[IF =D10 = 0,"" IF =D10 < DocVariable MonthEnd \@ d =D10+1 ""]	[IF =E10 = 0,"" IF =E10 < DocVariable MonthEnd \@ d =E10+1 ""]	[IF =F10 = 0,"" IF =F10 < DocVariable MonthEnd \@ d =F10+1 ""]
[IF =G10 = 0,"" IF =G10 < DocVariable MonthEnd \@ d =G10+1 ""]	[IF =A12 = 0,"" IF =A12 < DocVariable MonthEnd \@ d =A12+1 ""]					

Chem Report Chemist)
Fate Report Completed (Fate)
SAR/Tox Analysis (HH and Eco)
Hazard Reports (HH and Eco)

Engineering Reports (Engineer)
Exposure Reports (Exposure)
Risk Calculation (TI/Hazard)
Conceptual Model (engineer)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
[IF DocVariable MonthStart \@ dddd = "Sunday" 1 ""]				1 PMN comes in	2	3
4	5	6	7	8 Chemistry Meeting	9	10
11	12	13 Analog Table should be done	14	15 Hazard Meeting	16	17
18	19	20 Scoping meeting	21	22	23	24
25	26	27	28	[IF =D10 = 0,"" IF =D10 < DocVariable MonthEnd \@ d =D10+1 ""]29 Options Meeting	30[IF =E10 = 0,"" IF =E10 < DocVariable MonthEnd \@ d =E10+1 ""]	[IF =F10 = 0,"" IF =F10 < DocVariable MonthEnd \@ d =F10+1 ""]
[IF =G10 = 0,"" IF =G10 < DocVariable MonthEnd \@ d =G10+1 ""]	[IF =A12 = 0,"" IF =A12 < DocVariable MonthEnd \@ d =A12+1 ""]					

Chem Report Chemist)
Fate Report Completed (Fate)
SAR/Tox Analysis (HH and Eco)
Hazard Reports (HH and Eco)

Engineering Reports (Engineer)
Exposure Reports (Exposure)
Risk Calculation (TI/Hazard)
Conceptual Model (engineer)

Appointment

From: Dekleva, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bb17af28654434eb3c114bfca797997-Dekleva, Ly]
Sent: 10/6/2020 6:33:22 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]

Subject: Accepted: FW: TSCA Section 5 EPA Meeting
Location: **Ex. 6 Conference Code**
Start: 10/8/2020 6:30:00 PM
End: 10/8/2020 7:30:00 PM
Show Time As: Busy

Appointment

From: Dekleva, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bb17af28654434eb3c114bfca797997-Dekleva, Ly]
Sent: 10/6/2020 6:33:16 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]

Subject: Meeting Forward Notification: FW: TSCA Section 5 EPA Meeting

Start: 10/6/2020 7:00:00 PM
End: 10/6/2020 7:30:00 PM
Show Time As: Busy

Your meeting was forwarded

Dekleva, Lynn has forwarded your meeting request to additional people.

Meeting

FW: TSCA Section 5 EPA Meeting

Meeting Time

Thursday, October 8, 2020 2:30 PM - Thursday, October 8, 2020 3:30 PM

Recipients

Henry, Tala,Le, Madison,Camacho, Iris,Fehrenbacher, Cathy

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Appointment

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]
Sent: 10/6/2020 6:33:15 PM
To: Tala Henry (Henry.Tala@epa.gov) [Henry.Tala@epa.gov]; Le, Madison [Le.Madison@epa.gov]; Camacho, Iris [Camacho.Iris@epa.gov]
CC: Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting
Attachments: ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf
Location: Ex. 6 Personal Privacy (PP) - conference code/call in number

Start: 10/8/2020 6:30:00 PM
End: 10/8/2020 7:30:00 PM
Show Time As: Tentative

-----Original Appointment-----
From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Friday, October 2, 2020 8:24 PM
To: Franz, Christina; Dekleva, Lynn
Subject: FW: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

From: Franz, Christina
Sent: Thursday, October 01, 2020 12:58 PM
Required: TSCA Section 5 Group
Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie Mcmichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna); Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne
Subject: TSCA Section 5 EPA Meeting
When: Thursday, October 08, 2020 2:30 PM-3:30 PM.
Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

To join via webex: **Ex. 6 Personal Privacy (PP) - conference code/call in number**

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email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

TSCA Section 5 Work Group Meeting

AGENDA

Ex. 6 Personal Privacy (PP) - conference code/call in number | Access code Ex. 6 Personal Privacy (PP) - conference code/call in number

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)

[HYPERLINK Ex. 6 Personal Privacy (PP) - conference code/call in number

Time	Topic
2:30 p.m.	**Welcome and Introductions** • Antitrust Reminder • Agenda Review
	TSCA Discussion with EPA • OCSPP Reorganization • Safety Data Sheet Requirements on section 5 submissions • Access to engineering and health assessment reports • EPA's selection of analogues • 2020 EPA Stakeholder Meeting on Section 5 • 40 CFR 720 revisions
3:25 p.m.	**Next Steps**
3:30 p.m.	**Adjourn**

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. *Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings.* The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Council-sponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

- protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.; and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

- rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Revised 3/80 (single page version)
Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

Message

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]
Sent: 10/6/2020 1:52:02 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]
Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Monday, October 5, 2020 6:49 PM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Thanks,
Christina

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: Monday, October 05, 2020 3:47 PM
To: Franz, Christina
Subject: RE: TSCA Section 5 EPA Meeting

Hi Christina,

Ex. 5 Deliberative Process (DP)

Regards,
Lynn

Lynn Dekleva, Ph.D.

Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Monday, October 5, 2020 3:25 PM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: RE: TSCA Section 5 EPA Meeting

Hi Lynn--

Ex. 5 Deliberative Process (DP)

thanks!

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: Monday, October 05, 2020 3:19 PM
To: Franz, Christina
Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
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(202) 845-6261 (cell)
dekleva.lynn@epa.gov

-----Original Appointment-----
From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Friday, October 2, 2020 8:22 PM
To: Dekleva, Lynn
Subject: FW: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

-----Original Appointment-----
From: Franz, Christina
Sent: Thursday, October 1, 2020 12:58 PM

To: Franz, Christina; TSCA Section 5 Group
Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon Gerber; Kerry Coy; Elizer, Emily B
Subject: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

Formal agend to follow in the next few days.

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Message

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]
Sent: 10/5/2020 7:47:43 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]
Subject: RE: TSCA Section 5 EPA Meeting

Hi Christina,
If you have material you want to share we can do either WebEx or Teams. I'm fine with either.
I think we can easily cover the topics the Section 5 subgroup suggested:

- OCSPP Reorganization
- Safety Data Sheet Requirements on section 5 submissions
- Access to engineering and health assessment reports
- EPA's selection of analogues
- Is a 2020 EPA Stakeholder Meeting on Section 5 Planned?

Let's add 40 CFR 720 revision to the end of the agenda.

I would wait on the default assumption project until next meeting.

Regards,

Lynn

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
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(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Monday, October 5, 2020 3:25 PM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: RE: TSCA Section 5 EPA Meeting

Hi Lynn--

I will send the agenda shortly. Let me clarify though -- are you wanting to schedule this with Teams? That is fine if you do and we can work with that. Usually we use Webex, but I want to include the correct information on the agenda. If you have the information I should include on the agenda, please forward and I will list it there before sending to you.

thanks!

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: Monday, October 05, 2020 3:19 PM
To: Franz, Christina
Subject: RE: TSCA Section 5 EPA Meeting

If you have information you would like to share, I can send a Microsoft teams mtg. We will likely have a high level discussion on the default project. Not sure we will have anything to share by Thursday.

Lynn Dekleva, Ph.D.
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U.S. Environmental Protection Agency
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Washington, DC 20460
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dekleva.lynn@epa.gov

-----Original Appointment-----
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Sent: Friday, October 2, 2020 8:22 PM
To: Dekleva, Lynn
Subject: FW: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

-----Original Appointment-----
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Sent: Thursday, October 1, 2020 12:58 PM
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Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon Gerber; Kerry Coy; Elizer, Emily B
Subject: TSCA Section 5 EPA Meeting
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Formal agend to follow in the next few days.

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Subject: RE: TSCA Section 5 EPA Meeting

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Lynn Dekleva, Ph.D.
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Sent: 10/1/2020 3:55:28 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]
Subject: RE: Section 5 Discussion

Can we schedule something next Thursday 8-Oct from 2:30 -3:30? I have a recurring meeting during that time so I know the key individuals will be available during this time slot.

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
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(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Tuesday, September 29, 2020 11:38 AM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: Section 5 Discussion

Hi Lynn,

Apologies for the delay getting this list to you for Section 5 discussion. These are the topics we'd like to discuss. These include the two you mentioned. Please feel free to add others you would like to discuss that you may not have mentioned when we spoke. We know your time available is difficult to secure, but we hoped for an hour to an hour and a half if that might work with your schedule.

- OCSPP Reorganization
- Safety Data Sheet Requirements on section 5 submissions
- EPA section 5 defaults
- 40 CFR 720 revisions
- Access to engineering and health assessment reports
- EPA's selection of analogues
- Is a 2020 EPA Stakeholder Meeting on Section 5 Planned?

Thank you,

Christina

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second St., NE
Washington, D.C. 20002

202-249-6406 (o)
Ex. 6 Personal Privacy (PP) - personal phone
Christina_Franz@americanchemistry.com
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Message

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]
Sent: 4/29/2020 2:45:28 PM
To: Walls, Michael [Michael_Walls@americanchemistry.com]
Subject: RE: Invitation to "headline" May 13 ACC GlobalChem Webinar on New Chemicals

Mike,
I'd be glad to participate. I'll give you a call to discuss potential options sometime today or tomorrow morning.
Hope you and your family are surviving and thriving in this unusual time.
Regards,
Lynn

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
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1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Walls, Michael <Michael_Walls@americanchemistry.com>
Sent: Tuesday, April 28, 2020 10:47 AM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Cc: Gale, Kat <Kat_Gale@americanchemistry.com>; Pierce, Alison <Pierce.Alison@epa.gov>
Subject: Invitation to "headline" May 13 ACC GlobalChem Webinar on New Chemicals

Lynn, I hope you and your family are all doing well. I look forward to the day when we are back to at least "near-normal"!

As you know, ACC cancelled GlobalChem 2020 due to the pandemic. In its place, we have scheduled a series of webinars that we are calling the "GlobalChem 2020 Webinar Series." The webinars are being held each Wednesday beginning April 29, for 90 minute sessions beginning at 12 noon eastern. We very much appreciate the willingness of so many of the EPA staff to join our panels in these webinars.

We have tentatively scheduled Wednesday, May 13 for a session on the New Chemicals program, and I would like to formally invite you to provide the opening presentation/remarks at the session. You have been working hard to establish many process changes and efficiencies, and I know our audience would appreciate having your perspective on those changes and how submitters can provide the Agency the information it needs to make decisions on new chemicals.

I will be moderating the session. I thought that with you and perhaps one or two others from the new chemicals staff, we could have a robust discussion of the program and how it has changed since June, 2016, including the significant improvements in the average time to make decisions on submissions. As we were planning the original GlobalChem workshop session on new chemicals, we had a list of some six other EPA staff to include, and we would appreciate your input on who else we might invite. Rich Engler of Bergeson & Campbell is our fourth speaker, and he will provide a private sector perspective on the changes. In general, I think the session

can address key changes in the section 5 program, and challenges faced by EPA and submitters, including information requirements, assessment of risks, and practical tips.

With four speakers, we could have up to 15 minutes from each speaker, and then provide an opportunity for questions and answers. The webinars will be moderated by WebEx, so that everyone will be muted during the presentations and we can manage Q&A appropriately. We don't need extensive slide presentations, but I know the audience at GlobalChem has always appreciated having material that they can later reference. My hope would be that we could schedule a quick call for all the speakers to coordinate presentations.

Our intention is to record the webinar sessions for later viewing. The recorded sessions may capture PowerPoint presentation slides and audio of moderators and presenters, and/or still photographs of moderators and presenters. ACC requests that moderators and presenters agree to be identified by name and that their materials may be included in the recording. Presenters may request that specific material be withheld, or that their material or audio not be included in the final recording. The recordings in no way restrict the publication or dissemination of any material in any form by moderators or presenters, or others authorized by moderators or presenters.

I hope you will be able to join us as our headline speaker on May 13. I look forward to hearing from you. If you would prefer to speak directly, my cell number is Ex. 6 Personal Privacy (PP) - personal phone Thank you for your consideration! Regards, Mike

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Message

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Sent: 8/30/2019 7:44:33 PM
To: Walls, Michael [Michael_Walls@americanchemistry.com]
Subject: RE: Accessing pre-CDX PMN files

No issue Mike. It is always a pleasure to hear from you. Have a great weekend
Regards,
Lynn

From: Walls, Michael <Michael_Walls@americanchemistry.com>
Sent: Friday, August 30, 2019 11:09 AM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: RE: Accessing pre-CDX PMN files

Lynn, after I sent this message I became aware that EPA already has information on the website on accessing those old files. Sorry I did not check that before, and sorry to bother you.

Take care. Mike

From: Walls, Michael
Sent: Friday, August 30, 2019 10:52 AM
To: 'dekleva.lynn@epa.gov' <dekleva.lynn@epa.gov>
Subject: Accessing pre-CDX PMN files

Lynn, an ACC member company has a number of files that were created using the TSCA PMN generation and EPA submission software that was available before CDX became the standard. Unfortunately, the software doesn't seem to be available anymore, and they cannot open those files. These are files with extensions like filename.sup_tsca and filename.pmn_tsca.

Does EPA still provide access to the pre-CDX software, or know how companies could get the software? I imagine this might be an issue for a number of companies where prior submitted information could be relevant for current section 5 submissions.

Thanks very much for your help with this question. I hope you have a great Labor Day weekend – looks like the weather will be great for some rowing! Mike

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Message

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]
Sent: 6/18/2019 5:03:26 PM
To: rengler@lawbc.com
Attachments: Order Draft 29-May-2019.docx

Lynn Dekleva, Ph.D.
Science Advisor
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
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(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 204260

REGULATION OF A NEW CHEMICAL SUBSTANCE

Premanufacture Notice Number
Submission Date
Issuance Date

In accordance with the provisions of 15 U.S.C. § 2604(e),

[insert Company Name]

is authorized to manufacture, process, distribute in commerce, use, or dispose of the New Chemical Substance (NCS) in the United States only in accordance with the requirements and conditions described in this order.

Terms and conditions not otherwise defined in this order have the meaning assigned to them in TSCA or in regulations promulgated under TSCA. All terms and conditions of this order are enforceable by EPA and citizens under TSCA.

_____ _____
Office of Pollution Prevention and Toxics Date
U.S. Environmental Protection Agency

_____ _____
Name Date

_____
Title

_____
Company

Commented [BE1]: I recognize this front-page format is completely different than the prior boilerplate format. I am modeling it after EPA's CAA Title V Permits. Changing the way people perceive Section 5 orders is one of the primary drivers behind revising this boilerplate. It may get PMN submitters to "yes" faster if we can change the perception of what these orders mean (i.e., they are essentially permits).

Commented [BE2]: Instead of saying "Consent Order for Regulation…." – let's just start with "Regulation…" "Consent Order" has the perception that it stems from an enforcement action and the new chemical is tainted unfairly before it even goes to market. Section 5(e) is titled "Regulation Pending Development of Information," so the new title is not misleading or inappropriate.

Commented [BE3]: My strong recommendation is to change these "consent orders" to just "orders," which would only require an EPA signature. It gives EPA flexibility to issue a unilateral order if a submitter is taking too long to review and agree to the terms.

More importantly, Section 5(e) never uses the term "consent order" – so it's a term that EPA has created over the years. It's not necessary, potentially slows down our work, and limits our flexibility.

We can still work with submitters to get it right, like we do with Title V permit applicants. But, ultimately, we own this document and order.

Commented [BE4]: OGC, is this right?

Commented [BE5]: Our Title V permits have the signature line on the first page. I like this approach; otherwise, it is buried in the middle, given that we have numerous pages of appendices.

The statute requires EPA (1) to issue the order no later than 45 days before the expiration of the review period and (2) to notify the submitter in writing of the substance of the determination which underlies the order (it does not necessarily mean we have to share a draft order – just the substance of our determination, why we believe an order is necessary).

Commented [DL6]: Remove company signature for unilateral orders

Table of Contents

[TOC \o "1-3" \h \z \u]

Commented [BE7]: Flagging here that someone needs to update the ToC to conform with the heading edits in the body of the document (they did not automatically update).

Commented [DL8R7]: Done

Jurisdiction and General Provisions

This Order, pursuant to § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. § 2604(e)), is issued by the United States Environmental Protection Agency ("EPA" or "the Agency") regarding premanufacture notice ("PMN") P- [insert PMN number]) submitted by [insert Company/Submitter name] ("the Company") for the chemical substance [insert chemical name].

Based upon EPA's assessment of the New Chemical Substance, the administrative record, and determinations made herein, the Company may manufacture, process, distribute in commerce, use, or dispose of the New Chemical Substance in the United States only in accordance with the requirements and conditions described in this Order. The Company must comply with all provisions of this Order, including but not limited to, all appendices to this Order and all documents incorporated by reference.

Commented [BE9]: Again, how we frame this Section 5(e) order is important. Let's put the positive/permit language first and then the restrictive language.

Commented [BE10]: This is unnecessary legalese and mere surplusage because the entire document is an order (i.e., we do not need to say "It is hereby ordered…").

It is unlawful to fail or refuse to comply with any rule promulgated or order issued under TSCA (15 U.S.C. § 2614). Any person who violates the terms of this Order may be subject to both criminal and civil liabilities pursuant to 15 U.S.C. § 2615 and to specific enforcement and seizures pursuant to 15 U.S.C. § 2616.

Nothing in this order substitutes for or supersedes any statutory and regulatory requirements under TSCA. The Company must immediately inform EPA if it obtains any information concerning the New Chemical Substance that reasonably supports the conclusion that the New

Commented [DL11]: Removed 8e reporting requirement in this order

~~Chemical Substance presents a substantial risk of injury to health or the environment, as required under Section 8(e) of TSCA (15 U.S.C. § 2607(e)), unless the Company has actual knowledge that EPA has been adequately informed of such information. The notice must reference the appropriate PMN identification number for this substance and contain a statement that the New Chemical Substance is subject to this Order.~~

Unless otherwise expressly provided in this Order, terms used in this Order that are defined in TSCA or in regulations promulgated under TSCA shall have the meaning assigned to them in TSCA or in such regulations. Appendix 1 definitions shall apply to this Order and its appendices.

EPA's Determination

The following findings constitute the basis of this Order and Conditions for Manufacture issued under § 5(e) of TSCA:

☐ EPA has determined, pursuant to § 5(a)(3)(B)(i) and § 5(e)(1)(A)(i) of TSCA, ~~15 U.S.C. § 2604(a)(3)(B)(i) and 15 U.S.C. §2604(e)(1)(A)(i),~~ the information available to the Agency is insufficient to permit a reasoned evaluation of the health and/or environmental effects of the New Chemical Substance under the reasonably foreseen conditions of use.

OR

☐ EPA has determined, pursuant to Sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, ~~15 U.S.C. §§ 2604(a)(3)(B)(ii)(I) and 2604(e)(1)(A)(ii)(I),~~ in the absence of sufficient information to permit EPA to make a reasoned evaluation of the health and environmental effects of the New Chemical Substance, manufacture, processing, distribution in commerce, use, or disposal of the New Chemical Substance may present an unreasonable risk of injury to health and the environment.

OR

☐ EPA has determined, pursuant to Sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II) of TSCA, ~~15 U.S.C. §§ 2604(a)(3)(B)(ii)(II) and 2604(e)(1)(A)(ii)(II),~~ the New Chemical Substance is or will be produced in substantial quantity and that the New Chemical Substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the New Chemical Substance.

The basis for EPA's determination is attached as Appendix 2 to this order.

Requirements

Commented [BE12]: Not necessary (the whole document is the order)

The Order applies to all commercial manufacturing, processing, distribution in commerce, use and disposal of the New Chemical Substance, [insert PMN number], [insert chemical name] by the Company, as follows:

I. Testing and Reporting Requirements

The New Chemical Substance has the following testing and/or reporting requirements:

A. Triggered Testing

The Company is prohibited from manufacturing the New Chemical Substance beyond the cumulative domestic manufacturing volumes ("Manufacturing Limit") or Time ("Time Limit"), Table 1, unless the Company has submitted to EPA the final reports and data for the Required Triggered Testing, in accordance with the Testing Provisions outlined in Appendix 3.

Commented [DL13]: MG comment (Submission cant be enough...there needs to be some EPA acknowledgement

Table 1: Triggered Testing Requirements		
Manufacturing Limit (Kgs) or Time Limit	Study	Test Guideline

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B. Cumulative Volume Reporting Requirements

Until the Company submits all final reports and underlying data as specified in paragraph (A) above, the Company must report the cumulative manufacturing volume every [frequency of reporting] following submission of the Notice of Commencement (NOC). This report must be submitted [reporting conditions..... Ex by January 31st of the year subsequent to the reporting year].

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R .720.40.

C. Testing/Reporting

The Company must report [insert testing and/or reporting requirement] every [frequency and duration] following submission of the Notice of Commencement (NOC).

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. 720.40.

Prior to requiring the testing of New Chemical Substances using vertebrates, EPA considers reasonably available existing toxicity information; computational toxicology and bioinformatics; and high-throughput screening methods and their prediction models. Pursuant to TSCA section 4(h), EPA encourages the use of scientifically valid test methods and strategies (New Approach Methodologies or NAMs) to provide information of equivalent or better scientific quality and relevance.

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II. Terms of Manufacturing

A. Restriction on Manufacturing

The Company must manufacture the New Chemical Substance:

☐	In an enclosed process	☐	In the form of a powder
☐	In the form of a liquid	☐	In the form of a solid
☐	Below an annual volume of XXXX	☐	In the form of a liquid
☐	Below an aggregate volume of XXX	☐	In the form of a gas
☐	Above a Molecular Weight (Mn) of XXXXX	☐	Other
☐	In an application that does NOT generate a vapor, mist, or aerosol	☐	

Commented [DL14]: We can include the allowable manufacturing states and add a section that restricts the types of manufacturing

Commented [DL15]: Added this definition per MG suggestion

The Company ~~must~~ must not manufacture the New Chemical Substance:

☐	In open processes	☐	In the form of a powder
☐	In the United States (Import Only)	☐	In the form of a solid

Commented [BE16]: Should this be stated in permissive language instead and then we list what the manner in which the company may manufacture a substance? My understanding is usually we want to confine the manufacture to the form we reviewed and approved (and disallow the uses that we did not have information for or may present an unreasonable risk).

☐	Beyond an aggregate volume of XXXXXX	☐	In the form of a liquid
☐	Beyond an annual volume of XXXXXX	☐	In the form of a gas
☐	Below xxxx Molecular Weight	☐	In a form that is respirable
☐	In an application that generates a vapor, mist, or aerosol	☐	Other

B. ~~Prohibition~~ Limit on Manufacture by Others

1. The Company must not cause, encourage, or suggest the manufacture of the New Chemical Substance within the United States by any other person.
2. Termination of Certain Obligations Through Significant New Use Rule (SNUR) and Final SNUR Required Notification
    a. The Prohibition in the above Paragraph 1) expires according the provisions in Appendix 4.
    b. The Company must notify each person in writing whom it causes, encourages, or suggests the manufacture of the New Chemical Substance the existence of the final SNUR according to the conditions outlined in Appendix 4 and maintain a copy of such notification for 5 years.

C. Contract Manufacturing

The Contract Manufacturer(s) identified in the PMN may manufacture the New Chemical Substance pursuant to the requirements in the Order for Contract Manufacturers and in Appendix 5.

The Company may petition EPA pursuant to the Modification and Revocation of the Order Section to include additional Contract Manufacturers.

III. Terms of Processing

The Company's processing of the New Chemical Substance is, subject to the "Terms of Processing" in Appendix 6.

IV. Terms of Use

The Company's use of the New Chemical Substance is subject to the "Terms of Use" in Appendix 7.

V. Terms of Distribution

The Company's distribution of the New Chemical Substance to another person is subject to the Terms of Distribution in Appendix 8.

VI. Temporary Transport and Storage

The Company's distribution (transport) of the New Chemical Substance for temporary storage must be pursuant to the following limitations:

A. Containers containing the New Chemical Substance must be sealed.

B. Containers must be labeled with the following information and should not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. § 1801 et. seq.) and regulations issued under that Act by the Department of Transportation:

   1. The identity of the New Chemical Substance.
   2. The name and address of the manufacturer or responsible party who can provide additional information on the substance and any appropriate emergency procedures.
   3. Identification of health, environmental or exposure hazards and precautionary measure(s) for the New Chemical Substance.

VII. Terms of Disposal

The Company's disposal of the New Chemical Substance and any waste stream containing the New Chemical Substance must follow the below conditions, as indicated by the checked boxes:

☐ The New Chemical Substance ~~or~~ any waste stream containing the New Chemical Substance must be disposed of using the method(s) described in the PMN.

☐ The New Chemical Substance ~~and~~ or any waste stream containing the New Chemical Substance must be disposed of according to the Terms of Disposal in Appendix 9.

☐ The New Chemical Substance or any waste stream containing the New Chemical Substance must not be disposed of or released to the environment.

VIII. Release to Water

☐ The Company is prohibited from any release of the New Chemical Substance, or any waste stream containing the New Chemical Substance, into the Waters of the United States.

☐ The Company is prohibited from any release of the New Chemical Substance, or any waste stream containing the New Chemical Substance into the Waters of the United States:

A. Without the application of one or more of the following specified treatment technologies to achieve a [xxxx%] removal efficiency either by the discharger or, in the case of a release through publicly-

owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

Chemical precipitation and settling;
Biological treatment (activated sludge or equivalent) plus clarification;
Stream stripping;
Resin or activated carbon adsorption; and
Chemical destruction or conversion;

B. ~~Primary wastewater treatment~~ Without primary wastewater treatment, and secondary wastewater treatment as defined in 40 C.F.R. part 133.

C. If the discharge of the New Chemical Substance exceeds XXXXXX [ppb, ppm] [for XXXXX days in a month, for XXX consecutive days, XXXXX].

If for any reason the Company fails to comply with the release limitations applicable to the New Chemical Substance, the Company shall notify EPA, in writing, within 5 days of the release.

The notification must include the location of the release, an explanation and description of the reasons for the release, the amount of the release or deviation, all actions taken or to be taken to prevent or minimize the release and future release, and a schedule for implementation of any measures to be taken to prevent or mitigate effects of the release.

IX. Protection in the Workplace

The Company is prohibited from manufacturing, processing, and/or using the New Chemical Substance at any site controlled by the Company (including any associated packaging and storage, and during any cleaning or maintenance of equipment associated with the New Chemical Substance), without establishing and implementing a program to prevent workplace exposure to the PMN pursuant to the Protection in the Workplace requirements in Appendix 10.

X. Hazard Communication Program

The Company is prohibited from manufacturing, processing, and using the New Chemical Substance at any site (including any associated packaging and storage, and during any cleaning or maintenance of equipment associated with the New Chemical Substance), without establishing and implementing a hazard communication program consistent with the requirements in Appendix 11.

XI. Risk Notification

If EPA finds or determines, that despite the terms of this Order, the New Chemical Substance will present an unreasonable risk, or may present an additional unreasonable risk ~~of injury~~ to human health or the environment:

A. EPA will notify the Company, in writing, of its determination.
B. EPA may require the Company to undertake specific actions concerning further testing, and/or limits on manufacture, processing, distribution, use, and/or disposal of the New Chemical Substance,
C. The Company must incorporate this information and information on methods for protecting against such risk, on label and into the Safety Data Sheet (SDS), as described in 40 C.F.R. § 721.72(c), within 90 days and provide the updated SDS to all persons who receive or who have received the New Chemical Substance within the last 5 years, and

D. The Company must cease all manufacture, processing, distribution, use and disposal of the New Chemical Substance, within 2 weeks, unless:

1. The Company complies with all requirements of the notice,
2. The Company submits to EPA a written report, within the 2 weeks, refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the New Chemical Substance in accordance with the terms of this Order pending EPA's response to the Company's written report.
   a. The Company's report must be submitted as a support document for the PMN according to the procedures set out in 40 C.F.R. § 720.40.
   b. EPA will respond promptly to the Company's report, in writing.
   c. The Company, within 2 weeks of receipt of EPA's response, must comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the New Chemical Substance.

XII. Recordkeeping

The Company must maintain the records pursuant to the Recordkeeping Requirements outlined in Appendix 12 for 5 years after their creation date.

XIII. Automatic Sunset of Test Market Exemption ("TME"), Low Volume Exemption ("LVE"), and Low Release and Exposure Exemption ("LoREX")

The company is prohibited from the manufacture, processing, distribution in commerce, use, or disposal of the New Chemical Substance pursuant a "TME" under Section § 5(h)(1) of TSCA, 15 U.S.C. § 2604(h)(1), and 40 C.F.R. § 720.38, or a "LVE", or a "LoREX" under Section § 5(h)(4), 15 U.S.C. § 2604(h)(4) and 40 C.F.R. § 723.50(c)(1) and (2), respectively, as of the effective date of this Order.

XIV. Exemptions

The requirements of the Order apply to manufacture, processing, distribution in commerce, use, and/or disposal of the New Chemical Substance by the company, unless such requirements meet the exemptions pursuant to the terms of the exemptions outlined in Appendix 13. Recordkeeping requirements apply in all circumstances.

XV. Successor Liability Upon Transfer of Order

The Company may transfer its interest in the New Chemical Substance, including its right to manufacture the New Chemical Substance conferred by this Order, to a Successor in Interest pursuant to the Successor Liability Upon Transfer of Order requirements in Appendix 14.

Commented [BE17]: For the sake of efficiency and reducing unnecessary provisions, I deleted this section because the statutory inspection requirements speak for themselves, and our boilerplate language went beyond what TSCA authorizes EPA to do.

Commented [DL18R17]: I agree the request for pre-inspection information is not needed

XVI. Modification and Revocation of the Order

The Company may request at any time, in writing and based upon new information that EPA modify or revoke substantive provisions of this Order.

EPA may, at any time, upon the receipt of any information or evaluation of existing information, determine that the New Chemical Substance presents or may present an unreasonable risk of injury to health or the environment, and may issue a rule to regulate the substance or modify this Order to address any unreasonable risks.

EPA may modify or revoke substantive provisions of this Order, if EPA determines that specific substantive terms of this Order are no longer necessary to protect against a previously identified risk or upon consideration of new information, that the that the New Chemical Substance is not likely to present an unreasonable risk of injury to health or the environment.

XVII. OMB Control Number

The collection of information required in this Order has been approved under the currently valid OMB Control Number 2070-0012.Under the Paperwork Reduction Act and its regulations at 5 C.F.R. part 1320, particularly 5 C.F.R. § 1320.5(b), the Company is not required to respond to this collection of information unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB").

XVIII. Effect of the Order

A. Reservation of Rights

Except as specifically provided in this Order, nothing in this Order shall limit the power and authority of EPA to take, direct, or order all actions necessary to protect public health, welfare, or the environment. Further, nothing in this Order shall prevent EPA from seeking legal or equitable relief to enforce the terms of this Order, from taking other legal or equitable action as it deems appropriate and necessary, or from requiring the Company in the future to perform additional activities pursuant to TSCA or any other applicable law.

B. Effective Date

This Order shall be effective upon the date that EPA issues this order in accordance with TSCA Section 5(e)(1)(B).

This Order is effective upon expiration of the applicable review period.

Commented [BE19]: A submitter should not have to wait until the end of the review period to proceed. EPA just needs to make sure it complies with the time restrictions (issuing the order no later than 45 days before expiration of the applicable review period).

Commented [DL20R19]: This section B will be included in unilateral orders,

Commented [DL21]: This will be included in orders that both parties sign.

Commented [BE22]: It would be good practice for EPA to let a company review the draft order to ensure CBI is protected before we finalize it.

XIX. Potentially Useful Information

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~~A. Potentially Useful Information~~

The ~~following~~ "Potentially Useful Information" (Table 2) would assist in evaluating the potential effects caused by the New Chemical Substance~~:~~

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Table 2: Potential Useful Information

Information	Effects	Guideline(s)

~~The Company is not required to submit the "Potentially Useful Information" at a specified time or production volume.~~ The Company is not required to submit the "Potentially Useful Information.

Any potential useful information described in this Order was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the New Chemical Substance. Further, any testing/information identified by EOA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. Pursuant to TSCA section 4(h), which pertains to the reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (New Approach Methodologies or NAMs), if available, to generate potentially useful information.

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Appendix 1: Definitions

Unless otherwise expressly provided in this Order, the following definitions shall apply to the terms used in this Order:

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples may include, but are not limited to: clothing that covers the entire body, boots, coveralls, gloves, jackets, and pants.

"Company" means [insert company name].

"Commercial" means the use of a chemical substance or a mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry-cleaning establishment or painting contractor).

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

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"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture the New Chemical Substance under the conditions specified in Appendix V of this Order

"Enclosed Process" means a system the prevents release of the new chemical substance during manufacturing, processing or use.

"EPA" or "the Agency" means the United States Environmental Protection Agency, and any successor agencies.

"Equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to support a reasoned evaluation of the potential risk of injury to human health or the environment of the New Chemical Substance.

"Immediate use" means a use of a chemical substance that is under the control of, and used only by, a person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious" means that a chemical substance cannot cause chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States. This definition also applies to related noun and verb forms of "manufacture."

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"~~Non-enclosed~~Open process" ~~means~~ is ~~any~~ equipment ~~system~~ (such as an ~~open-top~~ reactor, storage tank, or mixing vessel) in which the new~~a~~ chemical substance ~~is manufactured, processed, or otherwise used where significant~~ is in direct contact ~~of the bulk chemical substance and the workplace air may occur~~with the atmosphere.

"Personal protective equipment" means any protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and respirators. Barrier creams are not included in this definition.

"New Chemical Substance" means the chemical substance described in the premanufacture notice submitted by the Company relevant to this Order.

"Predictable or Purposeful Release" means the routine or repeated activity that results in non-routine releases to water or non-routine releases to water that are not due to emergency conditions. EPA does not intend "predictable or purposeful" to limit the agency's strict liability authority under TSCA.

"Scientifically invalid" means departing in any significant way from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 C.F.R. part 792 such that the data do not support a reasoned evaluation of the health or environmental effects of the New Chemical Substance.

"SDS" means safety data sheet, the written listing of data for the chemical substance.

"Sealed" means a closed container that is physically and chemically suitable for long-term containment of the New Chemical Substance, and from which there will be no human exposure to, nor environmental release of, the New Chemical Substance during transport and storage.

"Site-limited intermediate" means an intermediate manufactured, processed, and used only within a site and not distributed in commerce other than as an impurity or for disposal. Imported intermediates cannot be "site-limited."

"Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the New Chemical Substance, including all ownership rights and legal liabilities, through a Transfer Document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the New Chemical Substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the New Chemical Substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3) and 40 C.F.R. § 720.3(z).

"Transfer Document" means the legal instrument(s) used to convey the interests in the New Chemical Substance, including the right to manufacture the New Chemical Substance, from the Company to the Successor in Interest.

"Waters of the United States" has the meaning set forth in 40 C.F.R. § 122.2.

"Work area" means a room or defined space in a workplace where the New Chemical Substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

Appendix 2: Basis for EPA's Determination

Insert basis for the determination from the following sections of the Health Report (Current) which will transition to the new "Human Health Hazard & Risk Report.

Human Effects Summary

1.1 Hazard Summary (Health Report)

1.1.1 Absorption/Metabolism

Basis

1.1 Hazard Summary (Health Report)

1.1.3 Hazard concerns

Environmental Effects Summary

Ecotox Report

Ecotox Factors

Comments

Risks to Workers

1.2 Exposure and Risk Summary (Health Report)

1.2.1 Workers

Risk to General Population

1.2 Exposure and Risk Summary (Health Report)

1.2.2 General Population

Risk to Consumers

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1.2 Exposure and Risk Summary (Health Report)

1.2.3 Consumers

Environmental Risks

Ecotox Report

Ecotox Factors

Ecotox Factors Comments

Include Human health hazard and precautionary statements.....

The following health and environmental hazard and precautionary statements must be included as part of the hazard communication program, appear on each label, and in Section 11 and Section 12 of SDS, if applicable.

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Appendix 3: Testing Provisions

I. Notice of Test Scheduling

A. The Company must notify, in writing, EPA Monitoring Assistance and Media Programs Division, Office of Enforcement and Compliance Assurance (OECA) and concurrently as a support document for the PMN using the procedures set out in 40 C.F.R. 720.40 the following:

1. The date when the study is scheduled to commence;
2. The name and address of the laboratory conducting the study;
3. The name and contact information (telephone number, email) of a person at the Company or laboratory whom EPA may contact regarding the study; and,
4. The PMN identification number for each substance and a statement that the substance is subject to this Order.

B. The written notice is to be submitted to EPA/OECA and as a support document to the PMN submission within 10 days of scheduling any study or within 15 days after the effective date of this Order, whichever is later.

C. The written notice should be submitted to EPA/OECA as follows:

Postal Mail Address

U.S. Environmental
U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Courier Delivery Address

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U.S. Environmental Protection Agency
GLP Section Chief – Pesticides, Water and Toxics Branch
Monitoring Assistance and Media Programs Division (2227A)
Office of Enforcement and Compliance Assurance
Room 7117B
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

II. Good Laboratory Practice Standards

Each test performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 C.F.R. part 792, and using methodologies generally accepted in the relevant scientific community at the time the test is initiated.

III. Modified Test Protocols

A. Prior to initiating any test that will use a modified version of a test protocol, the Company must first submit the test protocols to EPA and receive EPA's approval.
B. Test protocols must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.
C. EPA's acceptance of a test protocol does not constitute pre-acceptance of any future test results.

IV. Scientific Standards

Data must be produced or conducted using the best available science and must meet the following requirements:

A. The scientific information, technical procedures, measures, methods, protocols, methodologies or models employed to generate the information are reasonable for and consistent with the intended use of the information,
B. The information is relevant for EPA's use in making a determination about the New Chemical Substance

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C. The data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented with clarity and completeness,

D. The variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models are evaluated and characterized.

V. Submission of Test Reports and Underlying Data.

A. The Company must submit the final report (Public and CBI versions, if applicable) and all underlying data, within 90 days of the conclusion of the test.

B. The final report must contain the contents specified in 40 C.F.R. § 792.185.

C. Underlying data must be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" paragraphs in the applicable test guidelines.

VI. Raw Data

A. EPA may require the Company to submit raw data, such as slides and laboratory notebooks, if on the basis of the agency's professional judgment, that an adequate evaluation of the test cannot take place in the absence of these items.

B. The Company must provide raw data to EPA within 30 days of EPA's initial request for such data.

VII. Interim Results

A. EPA may require the Company to submit the results of an interim phase of a test.

B. The Company must provide interim results to EPA within 30 days of EPA's initial request for such results.

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VIII. Submission of Information

All test information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

IX. Effect of Equivocal Results

If EPA finds that the results are scientifically equivocal, the Company may be allowed to continue to manufacture the New Chemical Substance beyond the Production Limit. The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the New Chemical Substance, only by mutual consent of EPA and the Company.

Commented [DL23]: Check this language...it is confusing

X. Determination of Invalid Data.

A. If EPA or the Company finds that data is scientifically invalid, the Company must cease manufacture of the New Chemical Substance beyond the Production Limit.
   1. The Company must notify EPA, in writing, within 2 weeks of first finding or becoming aware that data generated by a test is scientifically invalid.
   2. EPA will notify the Company, in writing, of such a finding promptly upon EPA's receipt of a final test report and underlying data. identifying that test data is scientifically invalid.

B. EPA may allow the Company to manufacture the New Chemical Substance beyond the Production Limit if, EPA notifies the Company in writing and:
   1. The Company reconducts the testing and submits the final report and underlying data to EPA under the conditions outlined in Appendix II [Testing Provisions], or
   2. The Company submits a written report refuting EPA's determination within 4 weeks of receiving the determination of invalid data from EPA, or

3. The Company submits a written report to EPA explaining in detail, the circumstances which have caused, or will cause, development of scientifically invalid data within 2 weeks of providing the notice of Invalid Data to EPA.

Appendix 4: Termination of Certain Obligations Through Significant New Use Rule (SNUR) and SNUR Notification Requirements

I. Termination of Certain Obligations Through following a SNUR

The requirement in Section II B 1 [Terms of Manufacturing] in this Order expires 75 days after promulgation of a final SNUR under Section 5(a)(2) of TSCA and 15 U.S.C. § 2604(a)(2), unless the Company is notified by EPA of an action in a Federal Court seeking judicial review of the SNUR. The Prohibition will remain in effect until EPA notifies the Company that all Federal Court Actions have been resolved and the validity of the SNUR has been affirmed.

II. Final SNUR Required Notification

A. The Company must notify each person whom it causes, encourages or suggests the manufacture, processing, use or distribution of the New Chemical Substance the existence of the final SNUR.
B. The required notification must be in writing; reference the publication in the Federal Register or Code of Federal Regulations; and must specify all significant new uses under the SNUR which would require significant new use notice to EPA.
C. The written notification must be maintained for 5 years from the date of its creation.

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Appendix 5: Contract Manufacturers

I. Manufacture Solely for the Company

A. A Contract Manufacturer must be under contract to the Company to manufacture the New Chemical Substance solely for the Company.

B. The contract must specify the identity of the New Chemical Substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

II. Signed Order

A. Once EPA obtains a copy of the contract, EPA will prepare and transmit to each Contract Manufacturer a separate Order following the terms agreed to by the Company. The Company will be responsible for submitting to EPA the name, address, and telephone number of a responsible official of the Contract Manufacturer.

Commented [BE24]: Signature from the Contract Manufacturer will no longer be needed. EPA will just issue the order once EPA receives the information.

B. Each Contract Manufacturer must receive an executed copy of the Order for the Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture.

III. Contract Manufacturer Noncompliance

If the Company learns that the Contract Manufacturer has failed to comply with the Order for Contract Manufacturer, the Company must immediately take steps to cease the manufacture the New Chemical Substance, unless the Contract Manufacturer is in compliance with a SNUR for the New Chemical Substance, or unless the Company is able to document each of the following:

A. That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with the Order for Contract Manufacturer.

B. That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Order for Contract Manufacturer and will comply with those terms.

C. If, after receiving a statement of assurance from the Contract Manufacturer, the Company obtains knowledge that the Contract Manufacturer has failed to comply with the Order for Contract Manufacturer, the Company must cease the manufacture by the Contract Manufacturer and must notify the EPA. The Company is permitted to manufacture the New Chemical Substance by the Contract Manufacturer only upon written notification from EPA. .

Appendix 6: Terms of Processing

The Company shall NOT process the New Chemical Substance:

☐ In the form of a powder	☐ In non-enclosed processes
☐ In the form of a solid	☐ Beyond the site of manufacture
☐ In the form of a liquid	☒

☐ In the form of a gas	In an application method that generates a vapor, mist, or aerosol that results in inhalation exposure to workers
☐ In a manner that generates particles respirable to workers	☒ Other
☐ In a manner that reduces the Molecular Weight below {XXXX]	

Appendix 7: Terms of Use

The Company shall NOT use the New Chemical Substance:

Commented [BE25]: Per my comment in the body of the order, should we phrase it in the inverse (i.e., what the company can do)?

☐ In non-enclosed processes	☐ In the form of a powder
☐ Beyond the site of manufacture	☐ In the form of a solid
☐ Other than as an intermediate	☐ In the form of a liquid
☐ Other than as a site-limited intermediate	☐ In the form of a gas
☐ As an intermediate where of the concentration of the New Chemical Substance in the product exceeds XXXXX	☐ In an application method that generates a vapor, mist, dust or aerosol that results in inhalation to workers
☐ For non-industrial applications	☐ In an application that generates dust
☐ For Commercial Applications	☐ Other XXXXXXXX
☐ For Non-Commercial Applications	
☐ In Consumer Products	

Appendix 8: Terms of Distribution

The Company may distribute the New Chemical Substance to another person under the following conditions:

I. Export Notification

The Company must notify, in writing, any person to whom it distributes the New Chemical Substance, that the New Chemical Substance is subject to the notification requirements of TSCA Section 12(b), 5 U.S.C. § 2611(b), and 40 C.F.R. part 707, subpart D.

II. Written Agreement

Prior to distributing the New Chemical Substance to any person, the Company must obtain from that person a written agreement that the person will

A. Comply with the required terms and restrictions of the Protection in the Workplace, Hazard Communication Program, Terms of Processing, Use, Disposal and Release to Water of this Order
B. Not further distribute the New Chemical Substance to any other person except for the purposes of disposal or according to the terms and conditions for temporary transport and storage, or to an end user who will conduct no further processing of the New Chemical Substance.

III. Containers

A. Containers must be sealed and labeled according to the requirements in Appendix 11 Section II

B. Opening sealed containers, removing the New Chemical Substance or cleaning (including rinsing) the transport containers may occur only while the New Chemical Substance is in the possession and control of the Company or those having a written agreement with the Company.

IV. Termination of Certain Obligations through Significant New Use Rule (SNUR) and Final SNUR Required Notification

A. The Termination of Certain Obligations on others manufacturing the New Chemical Substance expires according the provisions summarized in Appendix 3.

B. The Company must notify each person whom it causes, encourages, or suggests the manufacture of the New Chemical Substance the existence of the final SNUR according to the conditions outlined in Appendix 3.

V. Recipient Non-Compliance

If the Company obtains knowledge that a recipient has failed to comply with any of the Terms of this Order, the Company must cease to supply the substance to that recipient, unless the Company is able to document:

A. The Company, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the Distribution requirements, or has engaged in a significant new use without submitting a significant new use notice (SNUN) to the EPA.

B. That, within 15 working days of notifying the recipient of the noncompliance, the Company received a written statement of assurance that the recipient is aware of the Terms of Distribution and will comply with those terms or is aware of the terms of the significant new use rule and will not engage in a significant new use without submitting a SNUN to EPA.

C. If the Company obtains knowledge that the recipient has failed to comply with any Distribution requirements or has engaged in a significant new use without submitting a SNUN after receiving a written statement of assurance from a

recipient, the Company must cease to supply the New Chemical Substance and must notify EPA of the failure to comply. The Company is permitted to resume supply of the New Chemical Substance to the recipient only upon written notification from EPA.

Appendix 9: Terms of Disposal

The New Chemical Substance, waste streams from manufacturing, processing and or use must be disposed of only by:

Disposal Method	New Chemical Substance	Waste Streams From		
		Manufacturing	Processing	Use
Incineration	☐	☐	☐	☐
Landfill RCRA Subtitle C	☐	☐	☐	☐
Landfill RCRA Subtitle D	☐	☐	☐	☐
Deep Well Injection	☐	☐	☐	☐
OtherXXXXXXXXXXXXX	☐	☐	☐	☐

Appendix 10: Protection in the Workplace

The Company is prohibited from manufacturing, processing and/or using the New Chemical Substance without establishing the following programs, as indicated by the checkboxes, to prevent workplace exposure:

☐	Engineering and Administrative Controls
☐	Dermal Personal Protective Equipment
☐	Respiratory Protection

I. Engineering and Administrative Controls

The company must implement engineering control measures (e.g. enclosure or confinement of the operation(s), general and local ventilation) or administrative control measures (e.g. workplace policies and procedures), where feasible, to prevent exposure to the New Chemical Substance consistent with the requirements of this section.

II. Dermal Personal Protective Equipment

A. The Company must ensure that each employee reasonably likely to be dermally exposed to the New Chemical Substance is provided with, and is required to wear, personal protective equipment ("PPE") that provides a barrier to prevent dermal exposure to the New Chemical Substance, including but not limited to:

1. Gloves
2. Full body chemical protective clothing

3. Chemical goggles or equivalent eye protection
4. Clothing which covers exposed areas of the arms, legs and torso.

B. PPE must be selected and used in accordance with the Occupational Safety and Health Administration's ("OSHA's") requirements at 29 C.F.R. §§ 1910.132, 1910.133, and 1910.138.

C. Gloves must be replaced at the end of each work shift during which they are exposed to the New Chemical Substance, and, if Permeation Testing as outlined in this section was used to establish impermeability, gloves may not be used for longer than for which they were tested.

D. Demonstration of Imperviousness

The Company must demonstrate that the PPE selected provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area. The Company may make this demonstration by any one or a combination of the following:

1. Permeation Testing

PPE must be tested alone and in combination with other chemical substances in the work area under the expected conditions of exposure. Permeation testing may be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results must be reported as the cumulative permeation rate as a function of time and documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 (2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials."

2. Manufacturer Specifications

Manufacturer specifications may establish the that PPE is impervious to the New Chemical Substance, alone and in combination with other chemical substances in the work area under the expected conditions of exposure.

The rationale regarding the selection of dermal protection, based on the demonstration of impervious or manufacturer specification, must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

III. Respiratory Protection

A. Respirators

The Company must ensure that each person subject to inhalation is provided with, and is required to wear, a National Institute for Occupational Safety and Health ("NIOSH")-certified [Particulate][Gas/Vapor][Combination Particulate and Gas/Vapor] respirator with an Assigned Protection Factor ("APF") of [Insert APF].

B. New Chemical Exposure Limit

1. As an alternative to compliance with the Order respirator requirements (listed above in IIIA of this Appendix), the Company may comply with the requirements of this New Chemical Exposure Limit (NCEL) section. Before the Company may deviate from the respirator requirements, however, the Company must:
   a. Submit the sampling and analytical method for the New Chemical Substance, verified in accordance with Appendix 15, as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.
   b. Obtain exposure monitoring results in accordance with Appendix 16.

c. Based on the exposure monitoring results, select, provide, and ensure use of the appropriate respiratory protection as specified in Section III B 3 a of this Appendix.

d. Submit the exposure monitoring results and selection criteria for respiratory protection as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

2. New Chemical Exposure Limit (NCEL)

a. The New Chemical Exposure Limit ("NCEL") for the New Chemical Substance is an interim level based on the limited information available to EPA at the time of development of this Order. The NCEL for the New Chemical Substance is as follows:

i. Time-Weighted Average ("TWA") Limit. The Company must ensure that no person is exposed to an airborne concentration of the New Chemical Substance in excess of _____ (the NCEL) as an 8-hour time-weighted average, without using a respirator in accordance with Section III B 3, NCEL Respiratory Protection, of this Appendix.

ii. Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift (NCELn) must be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

iii. Short-Term Exposure Limit ("STEL"). The Company must ensure that no person is exposed to an airborne concentration of the New Chemical Substance in excess of _____ as averaged over any 15-minute period, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit

section. [Note to Program Managers: Delete this paragraph if there is no STEL.]

b. Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final chemical-specific permissible exposure limit ("PEL") specifically applicable to this New Chemical Substance and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL will automatically become null and void. The requirements of this Order, however, are not negated by any pre-existing OSHA PEL applicable to the New Chemical Substance.

3. NCEL Respiratory Protection

a. Selection of Appropriate Respiratory Protection

The Exposure Monitoring is used to select the respiratory protection corresponding to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

Note to Program Managers: Copy the appropriate complete table from the Table of Respirators for NCELs in Appendix 19, and paste it here, then delete the Appendix

b. Reductions in Respiratory Protection

Before the Company may make any reduction in any respiratory protection pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least

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7 days apart, that the new respiratory protection is appropriate in accordance with Section III B 3 a, of this Appendix. Where the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements must be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

Commented [DS26]: Cite the paragraph (using the new numbering system discussed above).

Commented [DS27]: Unclear. Do you mean "must be taken at least 24 hours apart" or "may be taken 24 hours apart"?

c. Special Situations

i. Measurements Outside Quantitation Limits.

When a value less than the lower quantitation limit (LQL) of the analytical method (as described in Appendix 15) is measured, the Company must estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the upper quantitation limit (UQL) of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with Section II B 3 b of this Appendix.

ii. Cleanup and Remedial Actions

During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring, the Company must ensure that potentially

exposed persons use at least the respiratory protection specified in III B 3 a for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

d. NCEL Recordkeeping.

Whenever the Company elects to comply with this New Chemical Exposure Limit section, the Company must maintain the records in Appendix 18 NCEL Recordkeeping for 30 years after the date they are created, and the Company must make them available for inspection and copying by EPA in accordance with section 11 of TSCA.

Appendix 11: Hazard Communication Program

I. Requirements

A hazard communication program must be developed, implemented and maintained for the New Chemical Substance consistent with the requirements of the OSHA Hazard Communication Standard (29 CFR 1900.1200). The program must:

A. Be in writing.

B. Be developed and implemented in each workplace.

C. Be available upon request to all employees, contractors and their representatives.

D. List all chemical substances known to be present in the work area and chemicals which are subject to an order issued to the Company pursuant to Section 5 of TSCA, 15 U.S.C. § 2604, or subject to a SNUR issued pursuant to Section 5(a)(2) of TSCA, 15 U.S.C. § 2604(a)(2), and 40 C.F.R. part 721, subpart E. The list may be compiled for the workplace or for individual work areas.

E. Include methods the Company will use to inform employees (and contractors if reasonably likely to be exposed) of the presence of the New Chemical Substance in the workplace, the provisions of the Order and the hazard(s) associated with the New Chemical Substance, including the hazards of non-routine tasks involving the New Chemical Substance (e.g., cleaning of reactor vessels), and those associated with the New Chemical Substance contained in unlabeled pipes in their work area.

II. Labeling

A. The Company shall ensure that each container of the New Chemical Substance in the workplace is labeled. The labels must contain, at a minimum:

1. The identity by which the New Chemical Substance may be commonly recognized.

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2. The health and environmental hazards and precautionary measures for the New Chemical Substance
3. A statement of exposure and precautionary measure(s) for the New Chemical Substance
4. If the label is applied to a mixture of the New Chemical Substance with other chemicals, the health hazards, environmental hazards and precautionary measures to control worker exposure or environmental release which provide the greatest degree of protection. If the label or alternative form of warning differs from the applicable measures required under this Order, the Company must seek a determination of equivalency such alternative control measures pursuant to 40 C.F.R. 721.30.
5. Signs, placards, operating procedures, or other written materials may be used in lieu of affixing labels to individual process containers, if the alternative method identifies the containers to which it is applicable and conveys [the required] information. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.
6. Portable containers used for transfer of the New Chemical Substance need not be labeled if intended for immediate use of the employee who performs the transfer.
7. Labels, or alternative forms of warning, must be legible and prominently displayed.
8. Existing labels on containers of the New Chemical Substance obtained from persons outside the Company shall not be removed or defaced unless the container is immediately relabeled with the information specified in (A)(1-3) of this section.
9. Labels, or alternative forms of warning, must be printed in English. The information may be repeated in other languages.
10. Labels used for distribution in commerce must contain: the chemical substance identification; the health, environmental, and exposure hazards

and precautionary measures; and the name and address of the manufacturer or a responsible party who can provide hazard information and emergency procedures for the substance.

Labels shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. § 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

B. New hazard information. If the Company becomes aware of any significant new information regarding the hazards of the New Chemical Substance or ways to protect against the hazards, this new information must be added to the label within 90 days from the time the Company becomes aware of this information. If the New Chemical Substance is not currently being manufactured, processed, or used in the Company's workplace, the Company must add the new information to the label before the New Chemical Substance is reintroduced into the workplace.

III. Safety Data Sheet (SDS)

A. The Company must develop an SDS for the New Chemical Substance that contains, at a minimum, the following information:

1. The identity of the New Chemical Substance used on the container label;
2. Physical and chemical characteristics of the New Chemical Substance (e.g. vapor pressure, flash point);
3. Physical hazards including the potential for fire, explosion and reactivity;
4. Human and Environmental hazards;
5. Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 C.F.R. 721.30 provide substantially the same degree of protection as the identified control measures;

6. Signs and symptoms of exposure and any medical conditions which are expected to be aggravated by exposure;
7. The primary routes of exposure to the New Chemical Substance;
8. Precautionary measures to control worker exposure and/or environmental release, safe handling and appropriate engineering controls, work practices or personal protective equipment including the New Chemical Exposure Limits, if applicable;
9. Emergency first aid procedures;
10. Date of preparation or last revision; and
11. The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

B. The Company must update the SDS within 90 days if the Company becomes aware of any new hazard information.
C. The Company must ensure that an SDS is provided with initial shipments and the first shipment after an SDS is revised.
D. The Company must maintain a copy of the SDS in its workplace and ensure that it is readily accessible during each work shift to employees when they are in their work areas (29 CFR 1910.1200(g)(8)).
E. SDS must be printed in English. The information may be repeated in other languages.

IV. Employee Information and Training

The Company must ensure that employees are trained and provided with information on the New Chemical Substance. The information must be provided at the time of the employee's initial assignment to the work area containing the New Chemical Substance and whenever the New Chemical Substance is introduced into the area for the first time.

A. Training must include:
   1. Information required in the Hazard Communication Program;
   2. All operations in the work area where the substance is present;

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3. The location of the written hazard communication program and SDS;
4. The methods and observations that may be used to detect presence or release of the New Chemical Substance in or from an employee's work area;
5. The potential human health and environmental hazards of the New Chemical Substance;
6. Measures that employees can take to protect themselves and the environment including procedures implemented by the Company to control exposure including work practices, emergency procedures, PPE, and engineering controls; and
7. The labeling and SDS requirements.

Appendix 12: Recordkeeping

The Company shall maintain the following records until 5 years after the date they are created and must make them available for inspection and copying by EPA in accordance with Section 11 of TSCA, 15 U.S.C. § 2610:

I. Manufacture Volume

Records documenting the manufacture volume (including import) of the New Chemical Substance and the corresponding dates of manufacture.

II. Sites of Manufacture

Records documenting the address of all sites of manufacture, import, processing and use.

III. Sales and Transfers

Records documenting the date of all sales or transfers, the quantity of the New Chemical Substance sold or transferred, and the names and addresses (including

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shipping address, if different) outside the site of manufacture to whom the Company directly sells or transfers the New Chemical Substance.

IV. Protection in the Workplace

A. Protection in the Workplace Requirements

Records documenting establishment and implementation of a program pursuant to the requirements in Appendix 10 Protection in the Workplace.

B. Demonstration of Imperviousness

Records documenting the determinations that chemical protective clothing is impervious to the New Chemical Substance as outlined in Appendix I0 Section II.

C. NCEL

Records required by the New Chemical Exposure Limits Section of this Order, as outlined in Appendix 10 Section III if applicable

D. Hazard Communication Program

1. Records documenting establishment and implementation of a Hazard Communication Program as outlined in Appendix 11.
2. Copies of labels.
3. Copies of Safety Data Sheets required by the Hazard Communication Program Section in Appendix 11.

V. Terms of Manufacturing, Processing, Use, Distribution and Disposal

A. Terms of Manufacture

Records documenting compliance with the applicable manufacturing, processing, use, distribution and disposal restrictions in Reqirements Section of this Order.

B. Disposal Requirements

Records documenting compliance with the applicable disposal requirements including method of disposal, location of disposal sites, dates of disposal and volume of New

Chemical Substance. If the estimated disposal volume is not known or reasonable ascertainable by the Company, records must be maintained that demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirement(s).

C. Water Discharge Limits

Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation.

VI. Exemption Records

Records documenting compliance to the requirements for one or more of the exemptions [Appendix 13] that satisfy the statutory and regulatory requirements applicable to the exemption.

A. Export-Only Exemption

Any amounts or batches of the New Chemical Substance eligible for the Export-Only Exemption are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by Sections 12(a)(1)(B) and 12(b) of TSCA, 15 U.S.C. §§ 12(a)(1)(B) and 12(b), respectively.

B. Research & Development Exemption

Any amounts or batches of the New Chemical Substance eligible for the Research and Development Exemption are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 C.F.R. § 720.78(b).

Appendix 13: Exemptions

I. Export-Only Exemption

The requirements of this Order do not apply to manufacture, processing, or distribution in commerce of the New Chemical Substance "solely for export" in accordance with Sections 12(a) and 12(b) of TSCA, 15 U.S.C. 2611(a) and 2611(b), 40 C.F.R. § 720.3(s), and 40 C.F.R. part 707. The production volume produced under the "Export-Only Exemption", while not itself subject to the terms of this Order, counts towards the production trigger of the Required Triggered Testing Section I A of the Order, if applicable in this Order.

Commented [BE28]: I do not agree with the "once out, always out" policy. If you go back to export only, then you should still be exempt per the statute.

II. Research & Development ("R&D") Exemption

The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use, and disposal of the New Chemical Substance:

- in accordance with TSCA Section 5(h)(3), 15 U.S.C. § 2604(h)(3), 40 C.F.R. § 720.3(cc), and 40 C.F.R. § 720.36 or
- when manufactured solely for non-commercial R&D in accordance with 40 C.F.R. § 720.30(i).

III. Imported Articles Exemption

The requirements of this Order do not apply to the New Chemical Substance when it is imported as part of an "article" as defined at 40 C.F.R. § 720.3(c) and in compliance with 40 C.F.R. § 720.22(b)(1).

IV. Completely Reacted (Cured)

The requirements of this Order do not apply to quantities of the New Chemical Substance after they have been completely reacted (cured).

Appendix 14: Successor Liability Upon Transfer of Order

The Company may transfer its interest in the New Chemical Substance. The terms of this Order apply to a Successor in Interest, pursuant to the following requirements:

The "Notice of Transfer of Toxic Substances Control Act Section 5(e) Order" ("Notice of Transfer") must be fully executed before the Successor in Interest manufactures the New Chemical Substance.

The Transfer Document shall clearly state the effective date of the transfer of interest in the New Chemical Substance and must contain provisions which expressly transfer liability for the New Chemical Substance under the terms of this Order from the Company to the Successor in Interest.

Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the New Chemical Substance is manufactured.

The Notice of Transfer when fully executed shall be incorporated as, and become an enforceable part, of this Order.

The Successor in Interest is liable for compliance with the requirements and obligations of the Order as of the date of the transfer of interest in the New Chemical Substance.

The Notice of Transfer shall be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40, within 10 days of the effective date of the transfer.

Any new confidentiality claims asserted in the Notice of Transfer must be substantiated up front in accordance with TSCA § 14(c)(3). Guidance on substantiating CBI claims may be found at [HYPERLINK "https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission"]. A Notice of Transfer cannot modify a Confidential Business Information ("CBI") claim made by the PMN Submitter to assert a claim of confidentiality for information which has been released to the public by EPA because (1) PMN Submitter did not assert a CBI

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claim for that information, or (2) notwithstanding such a claim, EPA disclosed the information to the public in accordance with its authority under TSCA or applicable regulations.

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT

SECTION 5(e) ORDER

Company (Transferor)

PMN Number

1. Transfer of Interest in New Chemical Substance Pursuant to Terms of the Order. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") its interests in the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by an Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §2604(e).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, it has assumed all obligations conferred under the Order. The Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby (check one):

___ Reasserts

___ Relinquishes

___ Modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA, 15 U.S.C. § 2613, and 40 C.F.R. part 2, for the New Chemical Substance(s). Where "reasserts" or "relinquishes" is indicated, that designation will be deemed to apply to all such claims. Where "modifies" is indicated, such modification will be explained in detail in an attachment to this Notice of Transfer.

I certify that it is true and accurate that the Successor in Interest has:

(a) Taken reasonable measures to protect the confidentiality of the information;
(b) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(c) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Successor in Interest; and
(d) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.
CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN.

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed name of Authorized Official	
Title of Authorized Official	
Successor in Interest	Date
Signature of Authorized Official	Successor's Technical Contact
Printed Name of Authorized Official	Phone
Title of Authorized Official	Address
Address	City, State, Zip Code
City, State, Zip Code	

Appendix 15: Performance-Criteria for Sampling and Analytical Method

I. Applicability

A. For initial development and validation of the sampling and analytical method for the New Chemical Substance, all the requirements of this Appendix 15 Performance-Criteria for Sampling and Analytical Method apply.

B. For subsequent exposure monitoring conducted pursuant to Appendix XVI Monitoring Potential Exposure, only the following requirements apply: (4)(i), (4)(ii), (4)(iv)(II), (4)(v)(II), (8), and (9). Any deviation from the requirements of this Appendix 15 must be approved in writing by EPA.

II. Submission of Verified Method and Certification Statement

A. The Company must submit to EPA a copy of a validated sampling and analytical method for the New Chemical Substance which satisfies the criteria specified in this Appendix 15..

B. The method description must expressly state how the method compares with each quantitative requirement specified Performance-Criteria for Sampling and Analytical Method in this Appendix.

C. The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to the requirements of this Appendix.

D. To assist EPA in identifying the document, it must state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN #_____," after which the correct PMN number for this chemical substance must be stated.

E. This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

III. Verification of Analytical Method by Independent Third-Party Laboratory.

A. Verification

1. The Company must have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the New Chemical Substance, in accordance with the other requirements in this Appendix.
2. It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this Appendix.

B. Independent Reference Laboratory.

The independent reference laboratory must be a separate and distinct person (as defined at 40 C.F.R. 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

C. Accreditation

The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

D. Good Laboratory Practice Standards

The Laboratory verification of the analytical method for the New Chemical Substance must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 C.F.R.C.F.R. part 792. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 C.F.R. 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) Compliance with TSCA GLPS, however, is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

E. Analysis of Duplicate Samples

1. The Company must collect six duplicate samples (a total of 12) at the TWA concentration.
2. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the New Chemical Substance onto a sample collection device.
3. The duplicate samples must be collected on identical collection media, at the same time, and under the same conditions.
4. One set of six samples must immediately be analyzed by the Company, the other set of six samples must be analyzed by the Laboratory using the method developed by or for the Company.

F. Sample Storage Study

1. If the results of the analysis of duplicate samples pursuant do not satisfy the requirements in Comparison of Results, Section G of this Appendix, the Company must perform a sample storage study as follows:

a.Triplicate Samples.

i. The Company must collect six triplicate samples (a total of 18) at the TWA concentration.

ii. The samples must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the New Chemical Substance onto a sample collection device.

iii. The triplicate samples must be collected on identical collection media, at the same time, and under the same conditions. One set of six samples must immediately be analyzed by the Company.

b. Analysis After Sample Storage

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i. A sample storage evaluation must be performed with the two remaining sets of six samples.

ii. One set of six samples must be analyzed by the Laboratory using the method developed by or for the Company, and the other must be analyzed by the Company on the same day as the Laboratory analyzes its six samples.

iii. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

G. Comparison of Results

1. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in the Analysis of Duplicate Sample (Section E of this Appendix) or Sample Storage Study (Section F of this Appendix) must be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions must not exceed a 5% significance level. (See Appendix 17 - Statistical Analysis of NCELs Analytical Method Verification Results.)
2. The average of each set of six samples must be within 10% of the true value.
3. If the average of each set of six samples is not within 10% of the true value, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the true value.

H. Submission of Analytical Method Validation

This information must be submitted as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

IV. Accuracy

The sampling and analytical method must clearly demonstrate the following:

A. General

The sampling and analytical method, and all exposure monitoring data relied on by the Company, must be accurate to within +25% at a 95% confidence level for concentrations of the New Chemical Substance ranging from one half the NCEL to twice the NCEL.

B. NCEL Quantitation Limits

1. The analytical method should be capable of reliably quantifying the New Chemical Substance across the full range of reasonably likely exposures.
2. At a minimum, the analytical method must be capable of reliably quantifying from a lower quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL.
3. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with Measurements Outside Quantifications provisions of Appendix 10 Section III B I 3 c.

C. Lower Quantitation Limit Signal-To-Noise Ratio

1. The analytical method must be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level.
2. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.)
3. The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

D. Instrument Calibration.

1. Initial Calibration

a. For method development and validation (but not subsequent exposure monitoring), the initial calibration must at a minimum consist of five (5) calibration standards with a linear correlation of 0.95.
b. The five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (>0.5 x NCEL,< 1 x NCEL); one times the NCEL (1 x NCEL); between one and two times the NCEL (>1 x NCEL, < 2 x NCEL), and twice the NCEL (2 x NCEL).

2. Continuing Calibration
   a. During each week of both method development/validation and subsequent exposure monitoring, the Company must conduct both an initial instrument calibration and a continuing calibration.
   b. The Company must perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed.
   c. The continuing calibration sample must fall within + 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

E. Calculated Percent Recovery.
   1. Initial Calculation.
      a. For method development and validation, the Company must calculate the percent of the New Chemical Substance recovered by the analytical method from a sample containing a known quantity of the New Chemical Substance.
      b. The sample must be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor

pressure, by injecting the New Chemical Substance onto a sample collection device. (Such a sample is referred to as a "matrix spike").

c. The calculated percent recovery for each matrix spike must be greater than or equal to 75% and less than or equal to 125%.

d. Spike concentrations for the New Chemical Substance must be included in the sampling and analytical method submitted to EPA.

2. Subsequent Calculation

During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the New Chemical Substance onto a sample collection device, must be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

F. Sampling Device Capacity

1. The capacity of the sampling device must be tested, and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal loss.
2. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing.
3. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace.
4. Breakthrough is defined to have occurred when the concentration of the New Chemical Substance in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the New Chemical Substance is detected in the backup section of the sampler.

G. Sampling Device Desorption Efficiency

1. Where applicable, the desorption efficiency must be evaluated for the air sampling device.
2. A minimum of six air samples spiked with the New Chemical Substance at least the NCEL concentration must be prepared.
3. A recovery of at least 75% must be obtained for each of the six samples.

V. Precision

The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per Analysis of Duplicate Samples (Section III E of this Appendix) or Sample Storage Study (Section III F of this Appendix) must be less than 0.105, including allowance of 0.05 for error due to sampling.

VI. Interpretation of Accuracy and Precision Data

A. If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

B. For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m3 and the percent recovery is 75%, use the value 30 mg/m3/(0.75) = 40 mg/m3 when determining whether the levels are below the exposure limit.

VII. Representativeness

All sample conditions used to develop the methodology must mimic the actual workplace environment expected to be monitored. Conditions such as the temperature,

humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

VIII. Changes Affecting Validity

If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in Section IV and Section V of this Appendix are met.

Examples of possible changes include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive New Chemical Substance; or introduction of water/increased humidity to the workplace which could react with the New Chemical Substance and cause difficulties in collection and analysis.

IX. Comparability

All data and results must be reported in the same units of measurement as the NCEL.

X. Responsibility for Method Validity

The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this Appendix do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

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